TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete	**AJ.Mirza Pharma Karachi**
Manufacturer / Importer	**Importer**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO	In case of being Importers, the Firm should provide attested copies of the following documents also:		YES/NO	
1	National Tax Number (NTN) of the Firm for Income Tax, and	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA	1	Valid Drugs Sales License for the importer; and	YES	
2	Last year Income Tax Return of the Firm; and	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA	2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Sale Tax Registration Certificate of the Firm; and	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA	3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	Yes	
4	Certificate of Professional Tax of the Firm.	YES					4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
							5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	Yes	
							6	Valid DRAP approved Price List of the quoted items.	YES	

		Raw material and its source gradation **• Active and** **• Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer/importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**		**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate** **From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio-equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**			**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**			**Cold Chain Facility**		**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**		**1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only.** **1 mark per agreement up to a maximum of 5 marksPast Performance (Last two years).**	**Total Technical Score**
	Technical Evaluation Parameters	Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 12 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain	Satisfactory	nsatisfacto	1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	

S.No	Item Generic Name	Strength, Dosage form	Brand Name	40	30	10	5	0	9	6	0	5	0	1	0	5	70
29	Capecitabine Tab 500mg		Capegard	40	0	0	0	0	0	0	0	5	0	1	0	4	50
71	Fulvestrant 250mg Inj.		Fulvest	0	30	10	0	0	0	0	0	5	0	1	0	4	50
83	Imatinib 100mg Cap		Imatib	40	0	10	0	0	3	2	0	5	0	1	0	4	65
85	Imatinib 400mg Cap		Imatib	40	0	10	0	0	3	2	0	5	0	Sample not provided	0	4	64
100	Letrozole 2.5mg Tab		Letara	40	0	10	0	0	0	0	0	5	0	1	0	4	60
138	Oxaliplatin 100mg Inj.		Oxaliplatin	0	30	10	0	0	6	2	0	5	0	1	0	4	58
140	Oxaliplatin 50mg Inj.		Oxaliplatin	0	30	10	0	0	6	2	0	5	0	1	0	4	58
155	Pemetrexed 100mg Inj		Pemsoh	0	30	10	0	0	3	0	0	5	0	1	0	4	53
156	Pemetrexed 500mg Inj.		Pemsoh	0	30	10	0	0	3	0	0	5	0	1	0	4	53
3	Abiraterone 250 mg Tab		Abirone	0	30	10	0	0	0	2	0	5	0	Sample not provided	0	4	51
20	Bortezomib 3.5mg Inj.		Bortesoh	0	30	10	0	0	0	0	0	5	0	1	0	4	50
76	Granisterone 3mg Inj.		Granicip	40	0	0	0	0	0	0	0	5	0	1	0	4	50
96	Lenalidomide 10mg Cap.		lenmid	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	4	49
97	Lenalidomide 25mg Cap.		lenmid	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	4	49
177	Sorafenib 200mg Tab.		Soranib	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	4	39

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**AA PHARMA KARACHI**
Manufacturer / Importer	**Importer**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA
4	**Certificate of Professional Tax of the Firm.**	YES				

In case of being Importers, the Firm should provide attested copies of the following documents also:		YES/NO	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	YES	
6	Valid DRAP approved Price List of the quoted items.	YES	

	Technical Evaluation Parameters	Raw material and its source gradation •Active and •Inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

	Technical Evaluation Parameters			Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drug Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
74	**Gemcitabine**	**Inj. 200mg**	**Zefei**	0	30	10	0	0	3	4	0	5	0	1	0	4	57
75	**Gemcitabine**	**Inj. 1gm**	**Zefei**	0	30	10	0	0	3	4	0	5	0	1	0	4	57

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**CUNNINGHAM PHARMA LAHORE**
Manufacturer / Importer	**MANUFACTURER**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO	
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NO	
2	**Last year Income Tax Return of the Firm; and**	NO		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	YES	
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NO	
4	**Certificate of Professional Tax of the Firm.**	YES		4	Valid cGMP certificate issued by DRAP or cGMP inspection report by the DRAP	NO	Expired

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	NA	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	NA	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	NA	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	NA	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	NA	
6	Valid DRAP approved Price List of the quoted items.	NA	

	Technical Evaluation Parameters						
	Raw material and its source gradation •active and •inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

	Technical Evaluation Parameters			Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
57	**Eltrombopag**	**Tab. 25mg**	**Pagotras**	0	30	0	0	0	0	0	0	0	0	0	0	0	30
58	**Eltrombopag**	**Tab. 50mg**	**Pagotras**	0	30	0	0	0	0	0	0	0	0	0	0	0	30

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete	AMGOMED, Islamabad
Manufacturer / Importer	Importer

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	National Tax Number (NTN) of the Firm for Income Tax, and	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	N/A
2	Last year Income Tax Return of the Firm; and	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding	N/A
3	Sale Tax Registration Certificate of the Firm; and	YES		3	Valid DRAP Approved Price List of the quoted item/s.	N/A
4	Certificate of Professional Tax of the Firm.	YES				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and		
6	Valid DRAP approved Price List of the quoted items.	YES	

	Technical Evaluation Parameters	Raw material and its source gradation •Active and •Inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

				Category A – Approval By: •United States Food & Drug Administration (US-FDA) •European Medicines Agency (EMA) •Medicines & Healthcare Products Regulatory Agency (MHRA), UK •Therapeutics Goods Administration (TGA), Australia. •Pharmaceutical Medical Agency (PHARMAC), New Zealand •Pharmaceutical & Medical Devices Agency (PMDA), Japan •Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland •Health Canada •Health Sciences Authority (HAS), Singapore •National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: •Agência Nacional de Vigilância Sanitária (ANVIS), Brazil •Central Drugs Standard Control Organization (CDSCO), India •Drug Regulatory Authority, Pakistan •National Pharmaceutical Control Bureau (NPCB), Malaysia •Food & Drug Administration, South Korea •Ministry of Health, Egypt •Ministry of Health, Turkey •China Food & Drug Administration •Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 12 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
3	**Aberaterone**	**250mg tab**	**Abyga**	0	30	0	5	0	0	0	0	5	0	1	0	1	42
89	**Irinotecan**	**100mg inj**	**Irinotecan Medac**	40	0	0	0	0	0	0	0	5	0	1	0	1	47
103	**Leuprolide acetate**	**11.25mg inj**	**Lorelin Depot**	0	30	0	0	0	0	0	0	5	0	1	0	1	37
104	**Leuprolide acetate**	**3.75mg inj**	**Lorelin Depot**	0	30	0	0	0	0	0	0	5	0	1	0	1	37
138	**Oxaliplatin**	**100mg inj**	**Oxaliplatin Medac**	40	0	0	0	0	3	0	0	5	0	1	0	1	50
139	**Oxaliplatin**	**150mg inj**	**Oxaliplatin Medac**	40	0	0	0	0	3	0	0	5	0	1	0	1	50
140	**Oxaliplatin**	**50mg inj**	**Oxaliplatin Medac**	40	0	0	0	0	3	0	0	5	0	1	0	1	50
153	**Filgrastim**	**300mcg Inj**	**Amgofil**	0	30	0	0	0	0	0	0	5	0	1	0	1	37
181	**Temozolomide**	**100mg Cap**	**Temomedac**	40	0	0	0	0	0	0	0	5	0	1	0	1	47
182	**Temozolomide**	**20mg Cap**	**Temomedac**	40	0	0	0	0	0	0	0	5	0	1	0	1	47

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**AGP LIMITED, KARACHI**
Manufacturer / Importer	**IMPORTER/MANUFACTURER**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO	In case of being Importers, the Firm should provide attested copies of the following documents also:		YES/NO	
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	YES	1	Valid Drugs Sales License for the importer; and	YES	
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	YES	2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA	3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	**Certificate of Professional Tax of the Firm.**	YES		4	Valid cGMP certificate issued by DRAP or cGMP inspection report by the DRAP	N/A	4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
							5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	Yes	
							6	Valid DRAP approved Price List of the quoted items.	Yes	

	Technical Evaluation Parameters							
	Raw material and its source gradation **•Active and** **•Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval** **/ Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**	**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate** **From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS** **Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**	**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**	**Cold Chain Facility**	**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**	**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**

	Technical Evaluation Parameters			Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-i shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks		
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**	
135	**Ondansetrone**	**8mg Inj**	**Zofran**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	1	36	To be excluded due to contract manufacturing.
136	**Ondansetrone**	**8mg Tab**	**Zofran**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	1	36	To be excluded due to contract manufacturing.
138	**Oxaliplatin**	**100mg inj**	**Oxaliplatin Ebewe**	0	30	0	5	0	3	0	0	5	0	1	0	1	45	
139	**Oxaliplatin**	**150mg inj**	**Oxaliplatin Ebewe**	0	30	0	5	0	3	0	0	5	0	1	0	1	45	
141	**Paclitaxel**	**150mg inj**	**Paclitaxel Ebewe**	40	0	0	0	0	6	0	0	5	0	1	0	1	53	
142	**Paclitaxel**	**300mg Inj**	**Paclitaxel Ebewe**	40	0	0	0	0	6	0	0	5	0	1	0	1	53	

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**Martin Dow Specialties, Karachi**
Manufacturer / Importer	**Importer**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	N/A
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	N/A
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	N/A
4	**Certificate of Professional Tax of the Firm.**	YES				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	Yes	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	Yes	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	Yes	
6	Valid DRAP approved Price List of the quoted items.	Yes	

	Technical Evaluation Parameters	**Raw material and its source gradation** **•Active and** **•Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**	**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**	**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**	**Cold Chain Facility**	**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**	**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
75	**Granisetron**	**3mg/3ml Inj**	**Kytril**	40	0	10	0	0	3	2	0	5	0	1	0	0	61
76	**Granisetron**	**1mg Tab**	**Kytril**	40	0	10	0	0	3	2	0	5	0	1	0	0	61

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

	Name of the firm with Complete Address	**Macter International, Karachi**
	Manufacturer / Importer	**Manufacturer**

	Mandatory Requirements.	**YES / NO**		**In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:**		**YES/NO**
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	YES
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	YES
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NO
4	**Certificate of Professional Tax of the Firm.**	YES		4	Valid cGMP certificate issued by DRAP or cGMP inspection report by the DRAP	YES

	In case of being Importers, the Firm should provide attested copies of the following documents also:	**YES/NO**	
1	Valid Drugs Sales License for the importer; and	NA	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	NA	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	NA	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	NA	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	NA	
6	Valid DRAP approved Price List of the quoted items.	NA	

	Technical Evaluation Parameters			**Raw material and its source gradation** **•Active and** **•Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**			**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**			**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**			**Cold Chain Facility**		**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**		**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**
				Category A – Approval By: •United States Food & Drug Administration (US-FDA) •European Medicines Agency (EMA) •Medicines & Healthcare Products Regulatory Agency (MHRA), UK •Therapeutic Goods Administration (TGA), Australia. •Pharmaceutical Medical Agency (PHARMAC), New Zealand •Pharmaceutical & Medical Devices Agency (PMDA), Japan •Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland •Health Canada •Health Sciences Authority (HAS), Singapore •National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: •Agência Nacional de Vigilância Sanitária (ANVIS), Brazil •Central Drugs Standard Control Organization (CDSCO), India •Drug Regulatory Authority, Pakistan •National Pharmaceutical Control Bureau (NPCB), Malaysia •Food & Drug Administration, South Korea •Ministry of Health, Egypt •Ministry of Health, Turkey •China Food & Drug Administration •Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 12 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
64	**Erythropoeitin**	**2000 IU inj**	**MAC Epo**	0	30	0	0	0	0	0	0	5	0	1	0	1	37
64	**Erythropoeitin**	**10000 IU inj**	**MAC Epo**	0	30	0	0	0	0	0	0	5	0	1	0	1	37
152	**Pegfilgratim**	**6mg inj**	**Pegstim**	40	0	0	5	0	0	0	0	5	0	1	0	1	52
195	**Zoledronic Acid**	**4mg inj**	**Macdronic**	0	30	0	0	0	0	0	0	5	0	1	0	1	37

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

	Name of the firm with Complete Address	**Lab Diagnostics, Rawalpindi**
	Manufacturer / Importer	**Importer**

	Mandatory Requirements.	**YES / NO**		**In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:**		**YES/NO**
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA
4	**Certificate of Professional Tax of the Firm.**	YES				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	**YES/NO**	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	NO	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	NO	
6	Valid DRAP approved Price List of the quoted items.	YES	

	Technical Evaluation Parameters			**Raw material and its source gradation** **• Active and** **• Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**			**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate** **From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS** **Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**			**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**			**Cold Chain Facility**		**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**		**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**
				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
12	**Bendamustine**	**100 mg Inj.**	**Bendamustine**	0	0	0	0	0	0	0	0	5	0	1	0	2	8
19	**Bortezomib**	**3.5mg inj.**	**Bortezomib**	0	0	0	0	0	0	0	0	5	0	1	0	2	8
44	**Dacarbazine**	**200mg inj.**	**Dacarbazine**	0	0	0	0	0	0	0	0	5	0	1	0	2	8
95	**Lenalidomide**	**10mg Cap**	**Lenalidomide**	0	0	0	0	0	0	0	0	5	0	1	0	2	8
127	**Nab Paclitaxel**	**100mg inj**	**Nab Paclid**	0	0	0	0	0	0	0	0	5	0	1	0	2	8
149	**Peg-asparginase**	**3750 IU**	**Pegasparginase**	0	30	0	0	0	3	0	0	5	0	1	0	2	41

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**Getz pharma, Karachi**
Manufacturer / Importer	**Importer**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA
4	**Certificate of Professional Tax of the Firm.**	Yes				

In case of being Importers, the Firm should provide attested copies of the following documents also:		YES/NO	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	Yes	
6	Valid DRAP approved Price List of the quoted items.	YES	

	Technical Evaluation Parameters	**Raw material and its source gradation** **•Active and** **•Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**	**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate** **From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS** **Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**	**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**	**Cold Chain Facility**	**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**	**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
185	**Truastuzumab**	**440mg IV**	**Trastuget**	40	0	0	5	0	6	0	0	5	0	1	0	0	57

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	HIMMEL, LAHORE
Manufacturer / Importer	IMPORTER

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO	In case of being Importers, the Firm should provide attested copies of the following documents also:		YES/NO	
1	National Tax Number (NTN) of the Firm for Income Tax, and	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and		1	Valid Drugs Sales License for the importer; and	YES	
2	Last year Income Tax Return of the Firm; and	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.		2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Sale Tax Registration Certificate of the Firm; and	YES		3	Valid DRAP Approved Price List of the quoted item/s.		3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Certificate of Professional Tax of the Firm.	YES					4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
							5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	YES	
							6	Valid DRAP approved Price List of the quoted items.	YES	

	Technical Evaluation Parameters	Raw material and its source gradation •Active and •Inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drug Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 12 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
19	**Bortezomib**	**3.5mg inj**	**Bortezomib Pharmidea**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
16	**Bicalutamide**	**50mg tab**	**Casomid**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
29	**Carboplatin**	**150mg inj**	**Carplatu**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
30	**Carboplatin**	**450mg inj**	**Carplatu**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
194	**Zoledronic Acid**	**4mg inj**	**Zolonko**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
34	**Cisplatin**	**50mg inj**	**Cipintu**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
54	**Doxorubicin**	**50mg inj**	**Doxo Onko**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
21	**Cabazitaxel**	**60mg inj**	**Cabazitaxel Ever**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
70	**Fulvestrant**	**250mg inj**	**Fulvestrant Ever**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
77	**Ibrutinib**	**140mg cap**	**Ibrutix**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	3	38
57	**Eltrombopag**	**50mg tab**	**Elbonix**	0	30	0	5	0	0	0	0	5	0	1	0	3	44
37	**Crizotinib**	**250mg cap**	**Crizonix**	0	30	0	5	0	0	0	0	5	0	Sample not provided	0	3	43
3	**Abiraterone Acetate**	**250mg tab**	**Abiteron**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
95	**Linalidomide**	**10mg tab**	**Linamide**	0	30	0	5	0	0	0	0	5	0	1	0	3	44
96	**Linalidomide**	**25mg tab**	**Linamide**	0	30	0	5	0	0	0	0	5	0	1	0	3	44
97	**Lenvatinib**	**10mg tab**	**Lenvanix**	0	30	0	5	0	0	0	0	5	0	1	0	3	44
98	**Lenvatinib**	**4mg tab**	**Lenvanix**	0	30	0	5	0	0	0	0	5	0	1	0	3	44

127	**Nab-Paclitaxel**	**100mg inj**	**Nab-Xelpac**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
128	**Niltotinib**	**200mg cap**	**Nilonix**	0	30	0	5	0	0	0	0	5	0	1	0	3	44
136	**Osimertinib**	**80mg tab**	**Tegrix**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	3	38
142	**Palonosetrone**	**0.25mg inj**	**Paloxi**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
144	**Palbociclib**	**125mg tab**	**Palbonix**	0	30	0	0	0	0	0	0	5	0	1	0	3	39
167	**Regorafenib**	**40mg tab**	**Regonix**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	3	38
176	**Sorafenib**	**200mg tab**	**Soranix**	0	30	0	5	0	0	0	0	5	0	1	0	3	44
88	**Irinotecan**	**100mg inj**	**Irinotecan Aqvida**	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	3	48
139	**Oxaliplatin**	**50mg inj**	**Oxaliplatin Aqvida**	40	0	0	0	0	0	0	0	5	0	1	0	3	49
137	**Oxaliplatin**	**100mg inj**	**Oxaliplatin Aqvida**	40	0	0	0	0	0	0	0	5	0	1	0	3	49
140	**Paclitaxel**	**150mg inj**	**Paclitaxel Aqvida**	40	0	0	0	0	0	0	0	5	0	1	0	3	49
141	**Paclitaxel**	**300mg inj**	**Paclitaxel Aqvida**	40	0	0	0	0	0	0	0	5	0	1	0	3	49
52	**Docetaxel**	**20mg inj**	**Docetaxel Aqvida**	40	0	0	0	0	0	0	0	5	0	1	0	3	49
53	**Docetaxel**	**80mg inj**	**Docetaxel Aqvida**	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	3	48

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	Merixil Pharma, Islamabad
Manufacturer / Importer	Importer

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	National Tax Number (NTN) of the Firm for Income Tax, and	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA
2	Last year Income Tax Return of the Firm; and	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA
3	Sale Tax Registration Certificate of the Firm; and	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA
4	Certificate of Professional Tax of the Firm.	YES				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies;	YES	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	NO	Valid CGMP/COPP of Bendamustine, Zoledronic Acid, Paclitaxel, Lutrate, Filgrastim, Temozolamide are not present in the original bid. Not fulfilling the mandatory criterion.
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s.	NO	Valid free sale/ \COPPs not poresent for some items
6	Valid DRAP approved Price List of the quoted	No	

	Technical Evaluation Parameters	Raw material and its source gradation •Active and •Inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio-equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	i) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
13	**Bendamustine**	**100mg Inj**	**Seacross**	40	0	0	0	0	0	0	0	0	0	1	0	0	41
29	**Capecitabine**	**500mg tab**	**Capecitabine Normon**	40	0	10	0	0	0	0	0	5	0	1	0	3	59
53	**Docetaxel**	**20mg inj**	**Biodoce**	40	0	0	0	0	0	0	0	5	0	1	0	3	49
54	**Docetaxel**	**80mg inj**	**Biodoce**	40	0	0	0	0	0	0	0	5	0	1	0	3	49
68	**Exemestane**	**25mg tab**	**Normon**	40	0	10	0	0	0	0	0	5	0	1	0	3	59
84	**Imatnib**	**100mg tab**	**Imatinib Normon**	40	0	10	0	0	0	0	0	5	0	1	0	3	59
106	**Leuproline**	**22.5mg Inj**	**Lutrate**	Not fulfilling the mandatory criteria of valid CGMP and COPP from the country of origin	0	Bioeq study of Lipotec is provided while the quoted brand is Lutrate	0	0	0	0	0	5	0	1	0	3	9
135	**Ondansetron**	**8mg Inj**	Ondansetron Norma	40	0	0	0	0	0	0	0	5	0	1	0	3	49
142	**Paclitaxel**	**300mg Inj**	Biopac	Not fulfilling the mandatory criteria of valid CGMP and COPP from the country of origin. COPP expired	0	0	0	0	0	0	0	5	0	1	0	3	9
153	**Filgrastim**	**300mcg Inj**	Topneuter	Not fulfilling the mandatory criteria of valid CGMP and COPP from the country of origin. COPP expired	0	0	0	0	0	0	0	5	0	1	0	3	9
181	**Temozolomide**	**100mg Cap**	Temoergin	0	30	10	0	0	0	0	0	5	0	1	0	3	49
182	**Temozolomide**	**20mg Cap**	Temoergin	0	30	10	0	0	0	0	0	5	0	1	0	3	49
195	**Zoledronic acid**	**4mg Inj**	Zoledronic acid normon	40	0	0	0	0	0	0	0	5	0	1	0	3	49

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**PharmaSol**
Manufacturer / Importer	**Manufacturer**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	YES
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	YES
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	YES
4	**Certificate of Professional Tax of the Firm.**	YES		4	Valid cGMP certificate issued by DRAP or cGMP inspection report by the DRAP	YES

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	N/A	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	N/A	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	N/A	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	N/A	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	N/A	
6	Valid DRAP approved Price List of the quoted items.	N/A	

	Technical Evaluation Parameters	**Raw material and its source gradation** **• Active and** **• Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**	**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**	**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**	**Cold Chain Facility**	**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**	**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	i) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
2	**5 flurouracil**	**500mg/10ml inj**	**Flurosol**	0	30	0	0	0	0	0	0	5	0	1	0	2	38
17	**Bicalutamide**	**50mg tab**	**Bitamid**	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	2	47
29	**Capcitabine**	**500mg tab**	**Capcita**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
31	**Carboplatin**	**450 mg/45ml Inj.**	**Carbosol**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
35	**Cisplatin**	**50mg/50ml inj**	**Cispatin**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
44	**Cytarabine**	**500mg Inj**	**Cytorox**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
53	**Docetaxel trihydrate**	**20mg/5ml inj**	**Dotaxol**	40	0	0	0	0	0	0	0	5	0	1	0	2	48
54	**Docetaxel trihydrate**	**80mg/5ml**	**Dotaxol**	40	0	0	0	0	0	0	0	5	0	1	0	2	48
57	**Eltrombopag**	**25mg tab**	**Eltrom**	0	30	0	0	0	0	0	0	5	0	1	0	2	38
58	**Eltrombopag**	**50mg tab**	**Eltrom**	0	30	0	0	0	0	0	0	5	0	1	0	2	38
61	**Epirubicin Hcl**	**10mg/5ml inj**	**Rubisol**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
62	**Epirubicin Hcl**	**50mg/25ml inj**	**Rubisol**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
63	**Erlotinib**	**150mg tab**	**Erlonib**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
68	**Exemestane**	**25mg tab**	**Xemest**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
83	**Imatinib**	**100mg Cap**	**Glynib**	0	30	0	5	0	0	0	0	5	0	1	0	2	43
86	**Imatinib**	**400mg Cap**	**Glynib**	0	30	0	5	0	0	0	0	5	0	1	0	2	43
89	**Irinotecan**	**100mg inj**	**Irinosol**	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	2	47
94	**Lapatinib**	**250mg tab**	**Lepta**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
116	**Methotrexate**	**1g/40ml inj**	**Trexate**	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	2	47

115	**Methotrexate**	**10mg tab**	**Trexate**	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	2	47
117	**Methotrexate**	**50mg/2ml**	**Trexate**	40	0	0	0	0	0	0	0	5	0	1	0	2	48
129	**Nilotinib**	**200mg cap**	**Nitonib**	0	30	0	0	0	0	0	0	5	0	1	0	2	38
138	**Oxaliplatin**	**100mg inj**	**Oxalisol**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
140	**Oxaliplatin**	**50mg inj**	**Oxalisol**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
141	**Paclitaxel**	**150mg/25ml inj**	**Petaxel**	40	0	0	0	0	0	0	0	5	0	1	0	2	48
142	**Paclitaxel**	**300mg/50ml inj**	**Petaxel**	40	0	0	0	0	0	0	0	5	0	1	0	2	48
177	**Sorefinib tosylate**	**200mg tab**	**Sonib**	0	30	0	5	0	0	0	0	5	0	1	0	2	43
178	**Sunitinib maleate**	**50mg cap**	**Sunetic**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
181	**Temozolamide**	**100mg Cap**	**Zolomid**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
183	**Thalidomide**	**100mg cap**	**Thalimid**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	2	37
192	**Vinblastine Sulphate**	**10mg/10ml inj**	**Blasvin**	40	0	0	0	0	0	0	0	5	0	1	0	2	48
193	**Vincristine**	**1mg/1ml inj**	**Crisvin**	40	0	0	0	0	0	0	0	5	0	1	0	2	48
194	**Vincristine**	**2mg/2ml inj**	**Crisvin**	40	0	0	0	0	0	0	0	5	0	1	0	2	48

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**Pfizer Pakistan Limited, karachi**
Manufacturer / Importer	**Importer**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA
4	**Certificate of Professional Tax of the Firm.**	YES				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	YES	
6	Valid DRAP approved Price List of the quoted items.	YES	

	Technical Evaluation Parameters	**Raw material and its source gradation** **•Active and** **•Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**	**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**	**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**	**Cold Chain Facility**	**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**	**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drug Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
20	**Bortezomib**	**3.5mg inj**	**Pfizer Bortezomib**	**40**	0	0	0	0	0	0	0	**5**	0	1	0	2	48
141	**Paclitaxel**	**150mg Inj**	**Anzatext**	**40**	0	0	0	0	6	0	0	**5**	0	sample not provided	0	2	53
89	**Irinotecan**	**Inj. 100mg**	**Campto**	**40**	0	10	0	0	9	0	0	**5**	0	1	0	2	67
90	**Irinotecan**	**Inj, 40mg**	**Campto**	**40**	0	10	0	0	9	0	0	**5**	0	1	0	2	67
68	**Exemestane**	**25mg tab**	**Aromasin**	**0**	30	10	0	0	6	0	0	**5**	0	1	0	2	54
144	**Palbociclib**	**100mg cap**	**Ibrance**	**40**	0	10	0	0	9	0	0	**5**	0	1	0	2	67
145	**Palbociclib**	**125mg cap**	**Ibrance**	**40**	0	10	0	0	9	0	0	**5**	0	1	0	2	67
178	**Sunitinib**	**50mg cap**	**Sutent**	**40**	0	10	0	0	6	0	0	**5**	0	1	0	2	64
185	**Trastuzumab**	**440mg inj**	**Trazimera**	**40**	0	10	0	0	9	0	0	**5**	0	1	0	2	67

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

	Name of the firm with Complete Address	**Novartis, Karachi**
	Manufacturer / Importer	**Importer**

	Mandatory Requirements.	**YES / NO**		**In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:**		**YES/NO**
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA
2	**Last year Income Tax Return of the Firm; and**	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA
3	**Sale Tax Registration Certificate of the Firm; and**	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA
4	**Certificate of Professional Tax of the Firm.**	YES				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	**YES/NO**	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and		
6	Valid DRAP approved Price List of the quoted items.	No	

	Technical Evaluation Parameters			**Raw material and its source gradation** • Active and • Inactive **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**			**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**			**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**			**Cold Chain Facility**		**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**		**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**
				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drug Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 12 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
66	**Everolimus**	**5mg tab**	**Afinitor**	40	0	10	0	0	6	0	0	5	0	1	**0**	4	66
67	**Everolimus**	**10mg tab**	**Afinitor**	40	0	10	0	0	6	0	0	5	0	1	**0**	4	66
57	**Eltrombopag**	**25mg tab**	**Revolade**	40	0	10	0	0	3	0	0	5	0	1	**0**	4	63
58	**Eltrombopag**	**50mg tab**	**Revolade**	40	0	10	0	0	3	0	0	5	0	1	**0**	4	63
84	**Imatinib**	**100mg tab**	**Glivec**	40	0	10	0	0	6	0	0	5	0	1	**0**	4	66
173	**Ruxolitinib**	**5mg tab**	**Jakavi**	40	0	10	0	0	9	0	0	5	0	Sample not provided	**0**	4	68
174	**Ruxolitinib**	**15mg tab**	**Jakavi**	40	0	10	0	0	9	0	0	5	0	1	**0**	4	69
169	**Ribociclib**	**200mg tab**	**Kisqali**	40	0	10	0	0	6	0	0	5	0	1	**0**	4	66
94	**Lapatinib**	**250mg tab**	**Tykerb**	40	0	10	0	0	0	0	0	5	0	1	**0**	4	60

100	**Letrozole**	**2.5mg tab**	**Femara**	40	0	10	0	0	0	0	0	5	0	Sample not provided	**0**	4	59
149	**Pazopanib**	**400mg tab**	**Votrient**	40	0	10	0	0	6	0	0	5	0	1	**0**	4	66
175	**Ocreotide LAR**	**20mg inj**	**Sandostatin LAR**	0	30	10	0	0	3	0	0	5	0	1	**0**	4	53
176	**Ocreotide LAR**	**30mg inj**	**Sandostatin LAR**	0	30	10	0	0	3	0	0	5	0	1	**0**	4	53
129	**Nilotinib**	**200mg cap**	**Tasigna**	40	0	10	0	0	3	0	0	5	0	1	**0**	4	63
195	**Zoledronic Acid**	**4mg inj**	**Zometa**	40	0	10	0	0	0	2	0	5	0	Sample not provided	**0**	4	61

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**ONCOGENE PHARMA KARACHI**
Manufacturer / Importer	**MANUFACTURER**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO	In case of being Importers, the Firm should provide attested copies of the following documents also:		YES/NO	
1	National Tax Number (NTN) of the Firm for Income Tax, and	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	YES	1	Valid Drugs Sales License for the importer; and	NA	
2	Last year Income Tax Return of the Firm; and	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	YES	2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	NA	
3	Sale Tax Registration Certificate of the Firm; and	YES		3	Valid DRAP Approved Price List of the quoted item/s.	YES	3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	NA	
4	Certificate of Professional Tax of the Firm.	YES					4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	NA	
							5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	NA	
							6	Valid DRAP approved Price List of the quoted items.	NA	

	Technical Evaluation Parameters	Raw material and its source gradation •Active and •Inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

	Technical Evaluation Parameters			Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutics Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 12 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	i) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
3	**Abiraterone**	**250 mg Tab.**	**Abytiga**	0	30	0	0	0	0	0	0	5	0	1	0	0	36
4	**Abiraterone**	**500mg Tab.**	**Abytiga**	0	30	0	0	0	0	0	0	5	0	Sample not provided	0	0	35
29	**Capecitabine**	**500 mg Tab.**	**Pectibine**	40	0	0	0	0	0	0	0	5	0	Sample not provided	0	0	45
84	**Imatinib**	**100 mg Tab.**	**Imatigliv**	40	0	0	0	0	0	0	0	5	0	1	0	0	46
129	**Nilotinib**	**200 mg Cap.**	**Nilosigna**	0	30	0	0	0	0	0	0	5	0	1	0	0	36
149	**Pazopanib**	**400mg Tab.**	**Pazorene**	40	0	0	0	0	0	0	0	5	0	1	0	0	46

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	Roche Pakistan Limitted
Manufacturer / Importer	Importer

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	National Tax Number (NTN) of the Firm for Income Tax, and	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA
2	Last year Income Tax Return of the Firm; and	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA
3	Sale Tax Registration Certificate of the Firm; and	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA
4	Certificate of Professional Tax of the Firm.	YES				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	NA	
6	Valid DRAP approved Price List of the quoted items.	YES	

	Technical Evaluation Parameters	Raw material and its source gradation •Active and •Inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional De Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
5	**Adotrastuzumab**	**100mg inj**	**Kadcyla**	40	0	10	0	0	0	0	0	5	0	1	0	4	60
5	**Adotrastuzumab**	**160mg inj**	**Kadcyla**	40	0	10	0	0	0	0	0	5	0	1	0	4	60
6	**Alectinib**	**150mg cap**	**Alecensa**	40	0	10	0	0	3	0	0	5	0	1	0	4	63
9	**Atezolizumab**	**1200mg inj**	**Tecentriq**	40	0	10	0	0	9	0	0	5	0	1	0	4	69
15	**Bevacizumab**	**100mg/4ml inj**	**Avastin**	40	0	10	0	0	9	0	0	5	0	1	0	4	69
16	**Bevacizumab**	**400mg/16ml inj**	**Avastin**	40	0	10	0	0	9	0	0	5	0	1	0	4	69
131	**Obinutuzumab**	**1000mg inj**	**Gazyva**	40	0	10	0	0	9	0	0	5	0	1	0	4	69
158	**Pertuzumab**	**420mg inj**	**Perjeta**	40	0	10	0	0	0	0	0	5	0	1	0	4	60
159	**Pertuzumab/Trastuzumab**	**600/600mg inj**	**Phesgo**	40	0	10	0	0	6	0	0	5	0	1	0	4	66
160	**Pertuzumab/Trastuzumab**	**1200/600 mg inj**	**Phesgo**	40	0	10	0	0	6	0	0	5	0	1	0	4	66
161	**Polatuzumab**	**140mg inj**	**Polivy**	40	0	10	0	0	6	0	0	5	0	1	0	4	66
172	**Rituximab IV**	**100mg /10ml inj**	**Ristova**	40	0	10	0	0	9	0	0	5	0	1	0	4	69
171	**Rituximab IV**	**500mg /10ml inj**	**Ristova**	40	0	10	0	0	9	0	0	5	0	1	0	4	69
170	**Rituximab SC**	**1400mg/11.7ml**	**Mabthera**	40	0	10	0	0	9	0	0	5	0	1	0	4	69
185	**Trastuzumab**	**440mg IV inj**	**Herceptin**	40	0	10	0	0	9	0	0	5	0	1	0	4	69
186	**Trastuzumab**	**600mg SC inj**	**Herceptin**	40	0	10	0	0	9	0	0	5	0	1	0	4	69

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**PHARMEVO KARACHI**
Manufacturer / Importer	**IMPORTER**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	**National Tax Number (NTN) of the Firm for Income Tax, and**	NO		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	
2	**Last year Income Tax Return of the Firm; and**	NO		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	
3	**Sale Tax Registration Certificate of the Firm; and**	NO		3	Valid DRAP Approved Price List of the quoted item/s.	
4	**Certificate of Professional Tax of the Firm.**	NO				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	NO	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	NO	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	NO	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	NO	
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	NO	
6	Valid DRAP approved Price List of the quoted items.	NO	

	Technical Evaluation Parameters	Raw material and its source gradation •Active and •Inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

	Technical Evaluation Parameters			Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drug Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
	Bevacizumab	**100mg Inj**	**Bevec**	0	0	0	0	0	0	0	0	0	0	sample not provided	0	0	0
	Bevacizumab	**40mg Inj**	**Bevec**	0	0	0	0	0	0	0	0	0	0	sample not provided	0	0	0
	Rituximab	**100mg Inj.**	**Rituxim**	0	0	0	0	0	0	0	0	0	0	sample not provided	0	0	0
	Rituximab	**500mg Inj**	**Rituxim**	0	0	0	0	0	0	0	0	0	0	sample not provided	0	0	0
	Trastuzumab	**440mg Inj**	**Traszeptin**	0	0	0	0	0	0	0	0	0	0	sample not provided	0	0	0

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with Complete Address	**CCL Pharma Limitted Lahore**
Manufacturer / Importer	**Importer**

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO
1	National Tax Number (NTN) of the Firm for Income Tax, and	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and	NA
2	Last year Income Tax Return of the Firm; and	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.	NA
3	Sale Tax Registration Certificate of the Firm; and	YES		3	Valid DRAP Approved Price List of the quoted item/s.	NA
4	Certificate of Professional Tax of the Firm.	NO				

	In case of being Importers, the Firm should provide attested copies of the following documents also:	YES/NO	
1	Valid Drugs Sales License for the importer; and	YES	
2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	NO	
4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	NO	COPP of both products expired
5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	NO	
6	Valid DRAP approved Price List of the quoted items.	NO	

	Technical Evaluation Parameters	**Raw material and its source gradation** **•Active and** **•Inactive** **(For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades.** **Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement.** **Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company.** **Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.)** **Maximum marks for this criterion are 40.**	**Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate** **From an accredited lab of SRA countries (Stringent Regulatory Authorities).** **(Attach BE/BS** **Certificate with evidence as to its authenticity) from Category A countries.** **Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE** **Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid.** **Maximum marks for this criterion are 10.**	**Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)**	**Cold Chain Facility**	**Product Sample for Physical Evaluation.** **Samples will be examined per following parameters as mentioned in Annex-I:** **a. Labeling and Packing Rules 1986** **b. Outer packing** **c. Inner packing** **d. Physical appearance.** **Product which has unsatisfactory packing/labeling will be technically Disqualified.** **Maximum marks for this criterion are 1.**	**Past Performance (Last two years).** **1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks.** **3) The bidders have to undertake that they have never been blacklisted or debarred.** **Maximum marks for this criterion are 5.** **(iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.**	**Total Technical Score**

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 12 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
15	**Bevacizumab**	**100mg/4ml inj**	**Stivant**	0	0	0	0	0	3	0	0	0	0	Sample not provided	0	0	3
16	**Bevacizumab**	**400mg/16ml inj**	**Stivant**	0	0	0	0	0	3	0	0	0	0	Sample not provided	0	0	3
172	**Rituximab IV**	**100mg /10ml inj**	**Zytux**	0	0	0	0	0	0	0	0	0	0	Sample not provided	0	0	0
171	**Rituximab IV**	**500mg /10ml inj**	**Zytux**	0	0	0	0	0	0	0	0	0	0	Sample not provided	0	0	0

TECHNICAL EVALUATION PROFORMA, FOR PROCUREMENT OF MEDICINE FOR PROJECT TITLED " TREATMENT OF POOR CANCER PATIENTS"

Name of the firm with	Umar Pharma, Peshawar
Manufacturer / Importer	Importer

	Mandatory Requirements.	YES / NO		In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:		YES/NO	In case of being Importers, the Firm should provide attested copies of the following documents also:		YES/NO	
1	National Tax Number (NTN) of the Firm for Income Tax, and	YES		1	Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and		1	Valid Drugs Sales License for the importer; and	YES	
2	Last year Income Tax Return of the Firm; and	YES		2	Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition.		2	Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and	YES	
3	Sale Tax Registration Certificate of the Firm; and	YES		3	Valid DRAP Approved Price List of the quoted item/s.		3	Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and	YES	
4	Certificate of Professional Tax of the Firm.	YES					4	Valid cGMP/ Certificate of Pharmaceutical Product (COPP)/ Certificate of Medicinal Product (COMP) of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s, Certificate on company's own letter head shall not be acceptable. Non provision of the certificate shall lead to disqualification of the firm. and	YES	
							5	Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s. Non provision of this document shall lead to disqualification of the firm; and	NA	
							6	Valid DRAP approved Price List of the quoted items.	YES	

	Technical Evaluation Parameters	Raw material and its source gradation •Active and •Inactive (For API or finished product). i) The bidder (local manufacturer / multi-national manufacturer / importer) shall provide Analytical/Quality Assurance/ Approval Certificates for the manufacturing or marketing of each quoted product from any of the following categories of the Drug Regulatory Authority of the Country of Origin to achieve the corresponding evaluation grades. Certificate of Analysis/ / Approval / Quality Assurance Certificate duly verified/attested by official of the company shall be submitted along with the Technical Bid as a mandatory requirement. Importers must submit agency agreement/ approval with the original manufacturer duly attested/verified by official of the company. Detailed purchase trail of raw material from the claimed source shall be submitted (any proof of purchase e.g invoice etc.) Maximum marks for this criterion are 40.	Bio-Equivalence (BE) / Bio- Similar (BS) or Bio-waiver (BW) Study/Certificate From an accredited lab of SRA countries (Stringent Regulatory Authorities). (Attach BE/BS Certificate with evidence as to its authenticity) from Category A countries. Bio-Equivalence (BE) of the quoted product to be conducted against the originator. Original innovator products do not require bio- equivalence certificate and shall get 10 marks automatically. All other branded generics require BE Certificate, duly attested by an official of the company in Pakistan is to be submitted along with the Technical Bid. Maximum marks for this criterion are 10.	Clinical Trial/ Clinical studies assessing the safety and efficacy of the quoted drug. In case if the quoted item is Generic the studies must be performed on the Generic and not on the originator. (Must be an original research article)	Cold Chain Facility	Product Sample for Physical Evaluation. Samples will be examined per following parameters as mentioned in Annex-I: a. Labeling and Packing Rules 1986 b. Outer packing c. Inner packing d. Physical appearance. Product which has unsatisfactory packing/labeling will be technically Disqualified. Maximum marks for this criterion are 1.	Past Performance (Last two years). 1) Good Performance Certificates of these institutions must be produced in order to be eligible for 1 mark per institution upto a maximum of 5 marks. Only supply orders will not get any marks. 3) The bidders have to undertake that they have never been blacklisted or debarred. Maximum marks for this criterion are 5. (iv) Those firms who have not been regular in supplies for the Project "Treatment of Poor Cancer Patients" at HMC, Peshawar, TWO marks shall be deducted for poor past performance irrespective of substantial supplies or Performance at any other institute.	Total Technical Score

				Category A – Approval By: • United States Food & Drug Administration (US-FDA) • European Medicines Agency (EMA) • Medicines & Healthcare Products Regulatory Agency (MHRA), UK • Therapeutic Goods Administration (TGA), Australia. • Pharmaceutical Medical Agency (PHARMAC), New Zealand • Pharmaceutical & Medical Devices Agency (PMDA), Japan • Swiss Agency For therapeutic drugs (Swiss-medic), Switzerland • Health Canada • Health Sciences Authority (HAS), Singapore • National Administration of Drugs, Food & Medical technology (ANMAT), Argentina	Category B – Approved By: • Agência Nacional de Vigilância Sanitária (ANVIS), Brazil • Central Drugs Standard Control Organization (CDSCO), India • Drug Regulatory Authority, Pakistan • National Pharmaceutical Control Bureau (NPCB), Malaysia • Food & Drug Administration, South Korea • Ministry of Health, Egypt • Ministry of Health, Turkey • China Food & Drug Administration • Any other source not mentioned in Category-A	Study/certificate accepted/certified by a Category A Country Regulatory Authority. BE testing must be done using at least 24 subjects. Bio-waiver is acceptable only to injectable forms if issued by Category A Country.	BE/BS/BW certificate obtained for a quoted product from Category B Country (as mentioned at S No. 1 above).	No BE/BS/BW Certificate.	In case the study is published in Category "W" journal listed in HEC Journal Recognition System (HJRS) Database, 3 marks per original research article shall be awarded maximum up to 9 marks).	In case the study is published in Category "X" journal listed in HEC Journal Recognition System (HJRS) Database, 2 marks per original research article shall be awarded maximum up to 6 marks).	Studies/original article published in category "Y" journal of the HJRS shall not be awarded marks.	i) Certificate of compliance to cold chain standards issued by an authorized third party e.g. DRAP, PSQCA, PCSIR. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	ii) Non-Compliance to international reference standards or absence of Cold Chain requirements mentioned in Annex-I shall lead to disqualification of the relevant product that requires cold chain. In case if No cold chain facility for products requiring cold chain maintenance is present the firm / product shall be disqualified. The procuring entity reserves the right to visit any cold chain facility for physical inspection / verification	Satisfactory	Unsatisfactory	1) Substantial quantity of Supplies of anti-cancer medicines made to private sector Teaching Hospitals namely: The Aga Khan University Hospital, Karachi, Shaukat Khanum Hospital, Lahore/ Peshawar and CMH, Rawalpindi or to Hayatabad Medical Complex, Peshawar , Shifa Interntional hospital Islamabad, with Good/Satisfactory Performance Certificates from these institutions (mandatory). Marks shall only be provided to those who provide good performance certificate issued in the last 24 months. No marks will be given for supply orders only. 1 mark per agreement up to a maximum of 5 marks	
S.No	**Item Generic Name**	**Strength, Dosage form**	**Brand Name**	**40**	**30**	**10**	**5**	**0**	**9**	**6**	**0**	**5**	**0**	**1**	**0**	**5**	**70**
6	**Ansatrozole**	**1mg tab**	**Geneplex**	40	0	0	0	0	0	0	0	5	0	1	0	2	48
16	**Bicalutamide**	**50mg tab**	**Bicamide**	40	0	0	5	0	0	0	0	5	0	1	0	2	53
99	**Letrozole**	**2.5mg tab**	**Femaplex**	40	0	10	0	0	0	0	0	5	0	1	0	2	58
179	**Tamoxifen**	**10mg tab**	**Zymoplex**	0	30	0	0	0	0	0	0	5	0	1	0	2	38
180	**Tamoxifen**	**20mg tab**	**Zymoplex**	0	30	0	0	0	0	0	0	5	0	1	0	2	38