# MINUTES OF GRIEVANCE COMMITTEE MEETING FAISALABAD INSTITUTE OF CARDIOLOGY, FAISALABAD

A meeting of Grievance Committee for product of Angiography/Angioplasty Items F.Y. 2020-21 was held on 09.09.2020 at 10:10AM in the Office of the Medical Superintendent, Faisalabad Institute of Cardiology, Faisalabad.

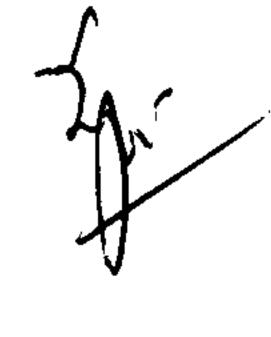
## ANGIOGRAPHY/ANGIOPLASTY ITEMS

1. M/s Popular International (Pvt) Ltd

Item #	Item Name	Brand Name	Manufactured By / Imported By		GC Observation	Remarks
51	STRIPS FOR GLUCOMETER (300 FOC GLUCOMETER REQUIRED COMPULSARY)	On call Plus	Acon USA	Invalid authority letter attached     Invalid free sale certificate attached	<ol> <li>valid authority letter</li> <li>attached</li> <li>valid free sale certificate</li> <li>attached</li> </ol>	Accepted

2. M/s Ferozsons Laboratories Limited

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
5	CORONARY STENT - DRUG ELUTING BUDGET STENTS FDA APPROVED (All diameters UPTO 38MM) According to DRAP Notification	Promus Element Plus Up to 38mm	Boston Scientific USA	<ul><li>1.Invalid Drug Registration</li><li>Certificate attached</li><li>2. Medical device registration</li><li>not attached</li></ul>	1. DRC not applicable for Medical Devices (07.04.20) 2. Application for Renewal to DRAP along with challan form attached (10.02.20)	Keep Pending process due to central purchase
10	DISTAL PROTECTION DEVICE (FILTERTYPE) ALL SIZES	Filter wire EZ	Boston Scientific USA	<ol> <li>Medical device registration not attached</li> <li>Invalid Provisional certificate attached</li> </ol>	<ol> <li>Medical device registration attached</li> <li>Provisional certificate not required</li> </ol>	Accepted
70	EMBOLIZATION COILS ALL SIZES	Pushable Coils	Boston Scientific USA	<ol> <li>Medical device registration not attached</li> <li>No previous experience with this institute</li> <li>Sample not provided</li> </ol>	<ol> <li>Medical device registration attached</li> <li>No previous experience with this institute</li> <li>The firm failed to provide the sample</li> </ol>	Rejected



# 3. M/s ATCO Pharma International Pvt Ltd

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
9	DIAGNOSTIC CATHETER ALL SIZES & ALL TYPES	Alvision	Alvimedica, Turkey	<ol> <li>Invalid drug registration certificate attached</li> <li>Medical device registration certificate not attached</li> </ol>	1. Invalid drug registration certificate attached (06.05.20) 2. Application for renewal for Medical device registration attached (20.04.20)	Keep Pending
29	PTCA BALLOON MONORAIL (SEMI COMPLIANT) - ALL SIZES	Fluydo	CID, Italy	Punjab govt. experience not attached	Experience of PIC, Lahore attached	Accepted
67	MP CATHETER ALL SIZES	Alvision	Alvimedica, Turkey	<ol> <li>Invalid drug registration certificate attached</li> <li>Medical device registration certificate not attached</li> </ol>	<ol> <li>Invalid drug registration certificate attached</li> <li>Medical device registration certificate not attached</li> </ol>	Keep Pending
69	PIGTAIL CATHETER ALL SIZES	Alvision		<ol> <li>Invalid drug registration certificate attached</li> <li>Medical device registration certificate not attached</li> </ol>	1. Invalid drug registration certificate attached 2. Medical device registration certificate not attached	Keep Pending

## 4. M/s Healthtec

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
16	GUIDING CATHETER ALL SIZES & ALL TYPES	Primum Hydrophilic Coated	Pendracare, Netherland	T.N.A Insufficient experience with this institute	End user reservation Insufficient experience with this institute	Rejected
37	TRANSFEMORAL SHEATH (SHEATH CATHETER WITH HAEMOSTATIC VALVE, GUIDE WIRE SPRING TYPE (J TYPE), DILATOR KINK RESISTANT, SELDINGER NEEDLE 18G WITH VALVE, IV CATHETER AND SCALPEL) ALL SIZES CE Approved Only	Femoral Sheath	SCW Medicath, China	Filter leakage	End user reservation	Rejected



38	TRANSRADIAL SHEATH (SHEATH CATHETER WITH HAEMOSTATIC VALVE, GUIDE WIRE (ST.TYPE), DILATOR KINK RESISTANT, SELDINGER NEEDLE 21G WITH VALVE, IV CATHETER AND SCALPEL)- ALL SIZES CE Approved Only	Radial Sheath	SCW Medicath, China	Filter leakage	End user reservation	Rejected
62	Glide Wire 0.035 (Ordinary) Straight / curved Hydrophilic 150CM	Poseidon Glide Wire 150cm	SP Medical, Denmark	No previous experience with this institute	No previous experience with this institute	Rejected
63	Glide Wire Exchange Length 0.035" & 0.025" 260CM Hydrophilic (Straight / Curved)	Poseidon Glide Wire 260cm	SP Medical, Denmark	No previous experience with this institute	No previous experience with this institute	Rejected
67	MP CATHETER ALL SIZES	Pointer	Pendracare, Netherland	Stiff and hard material	End user reservation	Rejected

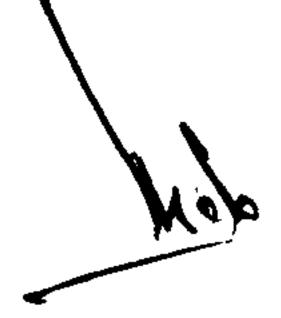
## 5. M/s Medtronic

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
6	STANDARD TOP OF THE LINE, DRUG ELUTING STENTS 2 <sup>nd</sup> Generation, FDA APPROVED (ALL LENGTH) According to DRAP Notification	Resolute Onyx	Galway, Ireland Medtronic	The brand quoted by the firm falls in category of 3 <sup>rd</sup> generation top of the line stents according to the DRAP notification while the firm quoted this brand in the category of 2 <sup>nd</sup> generation of stents	The brand quoted by the firm falls in category of 3 <sup>rd</sup> generation top of the line stents according to the DRAP notification while the firm quoted this brand in the category of 2 <sup>nd</sup> generation of stents	Keep Pending process due to central purchase
16	GUIDING CATHETER ALL SIZES & ALL TYPES	Launcher	Medtronic USA	Invalid free sale certificate attached	Valid free sale certificate attached	Accepted











#### 6. M/s AM Healthcare

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
42	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7	Cure	Anhui Anyu Latex Products Co. Ltd, China	1. Sample not provided 2. Authority letter from M/s care & cure to M/s A.M Healthcare attached while from M/s care & cur to manufacturer (M/s Anhui Anyu Latex Products Co. Ltd, China) not attached While fro M/s care & cure to another manufacturer name (M/s Yangzhou Goldenwell Medical device factory attached	1. Sample Provided, The GC Re-evaluated the sample, the quality was not up to the mark (poor quality) 2. Authority letter with discrepancy attached	Rejected
43	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7.5	Cure	Anhui Anyu Latex Products Co. Ltd, China	1. Sample not provided 2. Authority letter from M/s care & cure to M/s A.M Healthcare attached while from M/s care & cur to manufacturer (M/s Anhui Anyu Latex Products Co. Ltd, China) not attached While fro M/s care & cure to another manufacturer name (M/s Yangzhou Goldenwell Medical device factory attached	1. Sample Provided, The GC Re-evaluated the sample, the	Rejected

#### 7. M/s CorMed

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
60 a.	DELIVERY SYSTEM FOR PDA DEVICES ALL SIZES (7FR, 8FR, 9 FR)	Steerease For PDA	LifeTech, China	No previous experience with this institute	No previous experience with this institute	Rejected
60 b.	PDA DEVICES ALL SIZES	Cera PDA	LifeTech, China	No previous experience with this institute	No previous experience with this institute	Rejected









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61 a.	OCCLUDER DEVICES	Steerease For ASD	LifeTech, China	No previous experience with this institute	No previous experience with this institute	
	FOR ASD ALL SIZES			No previous experience with this	No previous experience with	Rejected
61 b	ASD DEVICES (SEPTAL OCCLUDER) ALL SIZES		LifeTech, China	institute	this institute	Rejected
64	Guide Wire Extra Stiff Exchange Length 0.035" 260CM (Super Stiff)		Merit Medical, USA	No previous experience with this institute	No previous experience with this institute	

8. M/s Yousaf and Co

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	<b>#</b>	DISPOSABLE LATEX GLOVES FOR EXAMINATION ALL SIZES (BOX OF 100)	Primax Examination Gloves all Size	Biomax , Malaysia	The brand mentioned on authority letter was MYKU examination gloves while on technically offer the brand name was mentioned Primax Examination Gloves	There is discrepancy in Authority Letter/Bogus Authority Letter	Rejected

9. M/s Safeway System Pakistan.

Item	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
<b>#</b>	THREE WAY STOP COCK - STANDARD	Welcare		<ul><li>1.Sample not provided</li><li>2. Medical device registration</li><li>certificate not attached</li></ul>	1.The firm failed to provide the sample 2. This item fall in category other than schedule "D" for which relaxation is given, therefore Medical Device registration certificate not required for this item yet.	Rejected
56	URINE BAG 2000 ML	lcare	Welford Manufacturing SDN BHD, Malaysia	Sample not provided	The firm failed to provide the sample	Rejected









10. M/s Intek Corporation

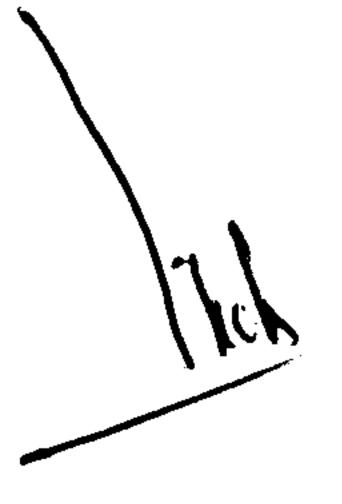
Item #	Item Name	Brand Name	Manufactured By / Imported By		GC Observation	Remarks
4	CLOT ASPIRATION CATHETER	Thrombuster li	Kaneka, Japan	1.Invalid Authority letter attached 2.Free sale certificate not attached	authority letter with     discrepancy attached     2.Free sale certificate attached	Rejected
38	TRANSRADIAL SHEATH (SHEATH CATHETER WITH HAEMOSTATIC VALVE, GUIDE WIRE (ST.TYPE), DILATOR KINK RESISTANT, SELDINGER NEEDLE 21G WITH VALVE, IV CATHETER AND SCALPEL)- ALL SIZES CE Approved Only	Introducer Kit	SHSMA Lepu, China	1. Sample not provided 2. Medical Device Registration certificate not attached 3. Free sale certificate not attached 4. Ambiguous authority letter attached (SHSMA & Lepu, Medical China both manufacturer authorized M/s Intek corporation for same products)	1. Sample Provided but no previous experience with this institute 2. Medical Device Registration certificate attached 3. Free sale certificate attached 4. Valid authority letter attached	Rejected
57	ATRIAL SEPTOSOMY BALLOON	Septosomy Balloon	Numed, USA	1.Medical Device Registration certificate not attached 2. Free sale certificate not attached	1.Medical Device Registration certificate attached 2. Free sale certificate attached	Accepted
59	COARCTATION OF AORTA STENTS Curved (ALL SIZES)	CP Stent	Numed, USA	<ol> <li>Medical Device Registration certificate not attached</li> <li>Free sale certificate not attached</li> </ol>	1. Medical Device Registration certificate attached  2 Free sale certificate attached	Accepted
60 a.	DELIVERY SYSTEM FOR PDA DEVICES ALL SIZES (7FR, 8FR, 9 FR)	PDA Delivery System	· •	<ol> <li>Ambiguous authority letter attached (SHSMA &amp; Lepu, Medical China both manufacturer authorized M/s Intek corporation for same products)</li> <li>No previous experience with this institute</li> <li>Sample not provided</li> <li>Free sale certificate not attached</li> </ol>	1. Valid authority letter attached 2. No previous experience with this institute 3. Sample Provided 4. Free sale certificate attached	Rejected
60 b.	PDA DEVICES ALL SIZES	Memopart PDA Occluder	SHSMA Lepu, China	. Ambiguous authority letter attached (SHSMA & Lepu, Medical China both manufacturer authorized M/s Intek corporation for same products)  2. No previous experience with this institute  3. Sample not provided  4. Free sale certificate not attached	<ol> <li>Valid authority letter attached</li> <li>No previous experience with this institute</li> <li>Sample Provided</li> <li>Free sale certificate attached</li> </ol>	Rejected

61 a.	DELIVERY SYSTEM FOR SEPTAL OCCLUDER DEVICES FOR ASD ALL SIZES	ASD Delivery System	SHSMA Lepu, China	1. Ambiguous authority letter attached (SHSMA & Lepu, Medical China both manufacturer authorized M/s Intek corporation for same products)  2. No previous experience with this institute  3. Sample not provided  4. Free sale certificate not attached	<ol> <li>Valid authority letter attached</li> <li>No previous experience with</li> </ol>	Rejected
61 b.	ASD DEVICES (SEPTAL OCCLUDER) ALL SIZES	ASD Occluder	SHSMA Lepu, China	1. Ambiguous authority letter attached (SHSMA & Lepu, Medical China both manufacturer authorized M/s Intek corporation for same products)  2. No previous experience with this institute	<ol> <li>Valid authority letter attached</li> <li>No previous experience with this institute</li> <li>Sample Provided</li> <li>Free sale certificate attached</li> </ol>	Rejected
66	PULMONARY VALVULOPLASTY BALLOONS ALL SIZES (SOFT PROFILE)	Tyshak	Numed, USA	not attached  2. Free sale certificate not attached  attached	1.Medical Device Registration for Tyshak-II and Tyshak Mini was attached in Technical Offer, the brand mentioned was only Tyshak  2. Free sale certificate attached	Rejected









11. M/s Friends Enterprises

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
42	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7	Protiex	Searle, Malaysia	1. Agreement between M/s Searle Switzerland and M/s Searle Pakistan not attached while agreement between M/s Searle Pakistan and M/s TG Sdn BHD Malaysia attached While on physically the address mentioned on the gloves of M/s Searle Switzerland and M/s Searle Pakistan 2. Punjab govt. experience not attached 3. Free sale certificate not attached 4. Sample quality not up to mark	1.Agreement between M/s Searle Switzerland and M/s Searle Pakistan not attached while agreement between M/s Searle Pakistan and M/s TG Sdn BHD Malaysia attached While on physically the address mentioned on the gloves of M/s Searle Switzerland and M/s Searle Pakistan. The Sample is not according to provided technical Proposal and given address G.C observed itself in detail. 2.Punjab govt. experience not attached 3. Free sale certificate not attached 4.End user reservation	Rejected
43	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7.5	Protiex	Searle, Malaysia	1. Agreement between M/s Searle Switzerland and M/s Searle Pakistan not attached while agreement between M/s Searle Pakistan and M/s TG Sdn BHD Malaysia attached While on physically the address mentioned on the gloves of M/s Searle Switzerland and M/s Searle Pakistan 2. Sufficient Punjab govt. experience not attached 3. Free sale certificate not attached 4.Sample quality not up to mark	1. Agreement between M/s Searle Switzerland and M/s Searle Pakistan not attached while agreement between M/s Searle Pakistan and M/s TG Sdn BHD Malaysia attached While on physically the address mentioned on the gloves of M/s Searle Switzerland and M/s Searle Pakistan. The Sample is not according to provided technical Proposal and given address G.C observed itself in detail.  2. Sufficient Punjab govt. experience not attached  3. Free sale certificate not attached  4. End user reservation	Rejected
ו ה	STRIPS FOR GLUCOMETER (300 FOC GLUCOMETER REQUIRED COMPULSARY)	Caresens	I-Selis, Rolea	1. No experience with this institute 2. Validity of Authority letter not mentioned on authority letter from M/s I-Sens, Korea to M/s Rafi Sultan	1. No experience with this institute 2. In DRAP importer of said item is M/s Mian Scientific while the firm provided the authority letter from M/s Rafi Sultan	Rejected







12. M/s Friends Enterprises

Sr#	Description	Firm Grievance	GC Observation	Remarks
1	Grievance against M/s Ali Medical Store.	The firm claims that their competitor for item No. 42 & 43 doesn't have registration with DRAP but the TAC approved the said items	Item No. 42 & 43 fall in category other than schedule "D" for which relaxation is given, therefore Medical Device registration certificate not required for this item yet.	Rejected
2.	Grievance against M/s Popular International	The firm claims that ON-CALL strips purchased by FIC are Chinese Product but its origin is shown as USA	Irrelevant grievance M/s Popular International is having the manufacturing documents of origin USA and China	Rejected

#### 13. M/s Cardiac Care

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
44	ECG CHEST ELECTRODE FOR ETT	Fiab	Italy	Poor conduction	End User Reservation	Rejected
45	ECG CHEST ELECTRODE FOR MONITORING — ADULT	Fiab	Italy	Poor conduction	End User Reservation	Rejected

#### 14. M/s Bilal International

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
40	CD WRITEABLE / REWRITEABLE COMPATIBLE WITH MACHINE	Maxell	Japan	<ol> <li>Sample not provided</li> <li>Authority letter not     attached</li> <li>Punjab Govt. experience     not attached</li> </ol>	<ol> <li>Sample Provided</li> <li>Authority letter not     attached</li> <li>Punjab Govt. experience     not attached</li> </ol>	Rejected
47	ECG ROLL (3 CHANNEL) 63MM	Local	Pakistan	<ol> <li>Sample not provided</li> <li>Authority letter not     attached</li> <li>Punjab Govt. experience     not attached</li> </ol>	<ol> <li>Sample Provided</li> <li>Authority letter not     attached</li> <li>irrelevant experience     attached</li> </ol>	Rejected
48	ECG ROLL (3 CHANNEL) 80MM	Local	Pakistan	<ol> <li>Sample not provided</li> <li>Authority letter not attached</li> <li>Punjab Govt. experience not attached</li> </ol>	1. Sample Provided 2. Authority letter not attached 3. irrelevant experience attached	Rejected

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15. M/s Usman & Co.

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Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
47	ECG ROLL (3 CHANNEL) 63MM	Medichart	China	Authority letter not attached	Authority letter attached The quoted product falls in Medical Devices, that's why DSL is required, so the firm failed to provide the DSL	Rejected
48	ECG ROLL (3 CHANNEL) 80MM	Medichart	China	Authority letter not attached	Authority letter attached The quoted product falls in Medical Devices, that's why DSL is required, so the firm failed to provide the DSL	Rejected

ltem #	perior Healthcare In Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
17	INFLATION DEVICE WITH (Y-CONNECTOR) (INTRODUCER NEEDLE) (TORQUER)	Blow Medas	USA	<ol> <li>Not user friendly</li> <li>Punjab Govt. experience not attached</li> <li>Medical device registration certificate not attached</li> <li>Invalid free sale certificate attached</li> </ol>	<ol> <li>End User Reservation</li> <li>Punjab Govt. experience not attached</li> <li>application of registration of medical devices to DRAP attached for Hope Pharma</li> <li>free sale certificate attached</li> </ol>	Rejected
42	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7	Guarda Powder Free with Aloe Gel Gentle Skin	Rosner Mauby Meditrade GmbH Germany	<ol> <li>Ambiguous Authority letter         (about validity) attached</li> <li>Sufficient Punjab Govt.         experience not attached</li> <li>Sample not provided</li> <li>Free sale certificate not attached</li> </ol>	<ol> <li>Authority letter attached</li> <li>insufficient Punjab Govt.</li> <li>experience attached</li> <li>the firm failed to provide</li> <li>the sample</li> <li>Invalid Free sale certificate</li> <li>attached</li> </ol>	Rejected
43	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7.5	Guarda Powder Free with Aloe Gel Gentle Skin	Rosner Mauby Meditrade GmbH Germany	1. Ambiguous Authority letter (about validity)attached 2. Sufficient Punjab Govt. experience not attached 3. Poor quality (Rupture during handling) 4. Free sale certificate not attached	<ol> <li>Authority letter attached</li> <li>insufficient Punjab Govt.</li> <li>experience attached</li> <li>end user reservation</li> <li>Invalid Free sale certificate</li> <li>attached</li> </ol>	Rejected

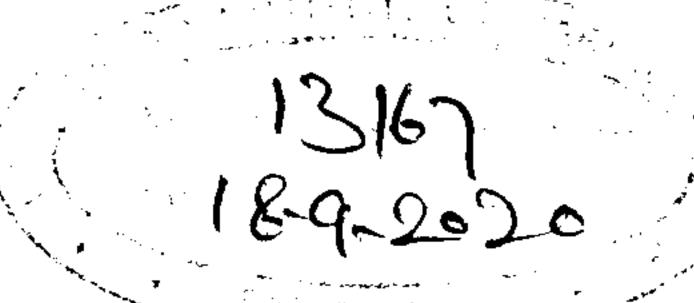
## 17. M/s Ali Medical Store

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
16	GUIDING CATHETER ALL SIZES & ALL TYPES	Falcon Guiding Catheter	Umbra Medical Products Inc. USA	<ol> <li>Stiff material</li> <li>No experience with this institute</li> </ol>	<ol> <li>End User Reservation</li> <li>No experience with this institute</li> </ol>	Rejected
52	SURGICAL TAPE (PAPER)-5 YARDS * 1" (4.5m)	Nichipore Surgical Tape	Nichiban Co. Ltd, Japan	<ol> <li>Invalid authority letter from M/s Nichiban co.ltd Japan to M/s unifroze attached</li> <li>Poor sticking</li> </ol>	1. authority letter not attached 2. End User Reservation	Rejected
55	THREE WAY STOP COCK - STANDARD	3-Way Stop Cock	Bicakcilar Dis Ticaret A.S, Turkey	Medical device registration certificate not attached	This item fall in category other than schedule "D" for which relaxation is given, therefore Medical Device registration certificate not required for this item yet.	Accepted

18. M/s Flowtronix System

Item #	Item Name	Brand Name	Manufactured By / Imported By	TAC Observations	GC Observation	Remarks
28	PTCA BALLOON MONORAIL NON- COMPLIANT-ALL SIZES	Appoio	Bros Med Co. Ltd Netherland	<ol> <li>Technically accepted subject to provision of Punjab govt. experience</li> <li>Free Sale Certificate not attached</li> </ol>	<ol> <li>Punjab govt. experience not attached</li> <li>Free Sale Certificate attached</li> </ol>	Rejected
29	PTCA BALLOON MONORAIL (SEMI COMPLIANT) - ALL SIZES	Artimes	Bros Med Co. Ltd	<ol> <li>Technically accepted subject to provision of Punjab govt. experience</li> <li>Free Sale Certificate not attached</li> </ol>	<ol> <li>Punjab govt. experience not attached</li> <li>Free Sale Certificate attached</li> </ol>	Rejected
54	TAPE FOR SKIN HYPO ALLERGIC ADHESIVE (TRANSPARENT) 3" X 10 YARDS (7.6cm x 9.1m)	3M 3" X 10 YARDS (7.6cm x 9.1m)		Authority letter not attached	Authority letter not attached	Rejected

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19. M/s Global Marketing Services

Item #	Description	Firm Grievance	GC Observation	Remarks
1	Grievance against M/s A&E Medical	The firm claims that the accepted items No. 37 and 38 of M/s A&E Medical was not having Provisional Certificate till 15.07.2019 so the firm doesn't fulfill the minimum criteria of one year marketing experience.		Rejected

Ms. Aisha Sultana, Pharmacist, FIC, Faisalabad.

Dr. Shahbaz Ahmed, Associate Prof. of Cardiac Surgery, FIC, Faisalabad. Mrs. Iqra Munir, Pharmacist, FIC, Faisalabad.

Dr. Shahid Abbas, Associate Prof. of Cardiology, FIC, Faisalabad. Engr. Touqir Nisar, Bio Medical Engineer, FIC, Faisalabad.

Dr. Zafar Abbas Khan, Medical Superintendent, FIC, Faisalabad.

