

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

A meeting of Grievance Committee for Angiography/Angioplasty Items was held on 24.08.2019 at 11:00AM in the Office of the Medical Superintendent, Faisalabad Institute of Cardiology, Faisalabad.

ANGIOGRAPHY/ANGIOPLASTY ITEMS

1. M/s Friends Enterprises

Item #	Item Name	TAC Observations	GC Observation	Remarks
48	DISPOSABLE LATEX GLOVES FOR EXAMINATION ALL SIZES (BOX OF 100)	T.N.A Agreement B/w Searle Switzerland & Searle Pakistan not attached Punjab Govt. experience not attached	Agreement B/w Searle Switzerland & Searle Pakistan not attached Punjab Govt. experience attached	Rejected
49	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7	T.N.A Agreement B/w Searle Switzerland & Searle Pakistan not attached Punjab Govt. experience not attached	Agreement B/w Searle Switzerland & Searle Pakistan not attached Punjab Govt. experience attached	Rejected
50	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7.5	T.N.A Agreement B/w Searle Switzerland & Searle Pakistan not attached Punjab Govt. experience not attached	Agreement B/w Searle Switzerland & Searle Pakistan not attached Punjab Govt. experience attached	Rejected
63	URINE BAG 2000 ML	T.N.A Authority letter not attached Govt. experience not attached	Authority letter not attached Govt. experience attached	Rejected

2. M/s Ali Medical Store

Item #	Item Name	TAC Observations	GC Observation	Remarks
48	DISPOSABLE LATEX GLOVES FOR EXAMINATION ALL SIZES (BOX OF 100)	T.N.A Thin material	End user reservation	Rejected
57	MANOMETER LINE- 200CM LONG	T.N.A Sample not provided	---	Rejected









3. M/s Health Tec

Item #	Item Name	TAC Observations	GC Observation	Remarks
12	DIAGNOSTIC CATHETER ALL SIZES & ALL TYPES FDA APPROVED	T.N.A Multiple recalls in Pharmacovigilance FDA certification not attached	As per end user the said catheter have already multiple recalls FDA Certificate is not attached	Rejected
14	DRUG ELUTING BALLOON ALL SIZES	T.N.A Sample not provided	---	Rejected
19	GUIDING CATHETER ALL SIZES & ALL TYPES	T.N.A No sufficient experience in this institute	In this Institute the experience is very limited	Rejected

4. M/s Husnain Pharma

Item #	Item Name	TAC Observations	GC Observation	Remarks
20	INFLATION DEVICE WITH (Y-CONNECTOR) (INTRUDUCER NEEDLE) (TORQUER)	T.N.A Not user friendly	End user not satisfied	Rejected
44	TRANSEMEMORAL SHEATH (INTRUDUCER SETS WITH HAEMOSTATIC VALVE, GUIDE WIRE DILATOR AND OBTURATOR) ALL SIZES	T.N.A Valve leak	End user reservation	Rejected

5. M/s Al-Waali Care Concepts

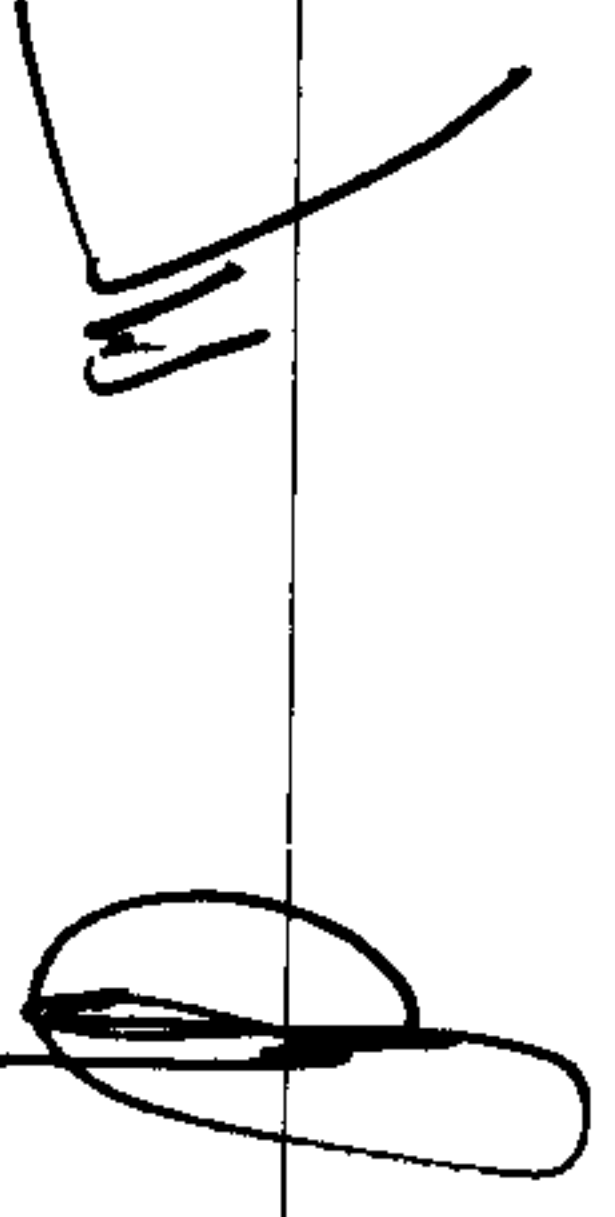
Item #	Item Name	TAC Observations	GC Observation	Remarks
49	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7	T.N.A Punjab Govt. experience not attached	Only Govt. Mozang Teaching Hospital experience Attached	Rejected
50	DISPOSABLE LATEX SURGICAL GLOVES STERILIZED (POWDER FREE) NO. 7.5	T.N.A Punjab Govt. experience not attached	Only Govt. Mozang Teaching Hospital experience Attached	Rejected

6. M/s B.Braun Pakistan

Item #	Item Name	TAC Observations	GC Observation	Remarks
9	CORONARY STENT - DRUG ELUTING 3rd Generation, Polymer Free FDA APPROVED/CE Mark(All Sizes)	K.P	K.P	---
17	GUIDE WIRE 150-160 CM STANDARD LENGTH 0.035" J TIP	T.N.A Registration of medical devices not attached	Registration of medical devices not attached	Rejected
18	GUIDE WIRE EXCHANGE LENGTH 0.035" 260CM J TIP	T.N.A Registration of medical devices not attached	Registration of medical devices not attached	Rejected
23	MANIFOLD 2 WAY	T.N.A Registration of medical devices not attached	Registration of medical devices not attached	Rejected
31	PTCA BALLOON MONORAIL NON-COMPLIANT-ALL SIZES	T.N.A DRC not attached Registration of medical devices not attached Punjab Govt. experience not attached	DRC attached Registration of medical devices attached Punjab Govt. experience not attached	Rejected

7. M/s Digital Imaging System

Item #	Item Name	TAC Observations	GC Observation	Remarks
6	CORONARY STENT - DRUG ELUTING 2nd Generation FDA APPROVED (All diameters UPTO 38MM)	K.P	K.P	---
7	CORONARY STENT - DRUG ELUTING 2nd Generation FDA APPROVED (All diameters 39-48MM)	K.P	K.P	---
8	CORONARY STENT - DRUG ELUTING 2nd Generation, latest versions with better trackability/deliverability FDA APPROVED (All length)	K.P	K.P	---


20	INFLATION DEVICE WITH (Y-CONNECTOR) (INTRODUCER NEEDLE) (TORQUER)	T.N.A Medical devices registration not attached Invalid provisional certificate attached	Application for Medical devices registration attached Subject to provision of Medical Devices Registration Certificate	Refer back to TAC
67	DELIVERY SYSTEM FOR PDA DEVICES ALL SIZES (7FR, 8FR, 9 FR)	T.N.A Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Rejected
68	DELIVERY SYSTEM FOR SEPTAL OCCLUDER DEVICES FOR ASD ALL SIZES	T.N.A Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Rejected
72	MUSCULAR VSD DELIVERY SYSTEM DEVICES ALL SIZES	T.N.A Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Rejected
73	MUSCULAR VSD DEVICES ALL SIZES	T.N.A Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Rejected
75	PDA AMPLATZER DEVICES ALL SIZES	T.N.A Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Rejected
77	ASD DEVICES (SEPTAL OCCLUDER) ALL SIZES	T.N.A Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Rejected
78	ADO II PDA DEVICES	T.N.A Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Rejected
79	DELIVERY SYSTEM FOR ADO II PDA DEVICES	T.N.A Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Authority letter not attached Brand Name not mentioned More than one manufacturer quoted	Rejected

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8. M/s Ferozsons Laboratories Limited

Item #	Item Name	TAC Observations	GC Observation	Remarks
14	DRUG ELUTING BALLOON ALL SIZES	T.N.A DRC not attached Punjab Govt. experience not attached Free sale certificate not attached Medical devices registration not attached	DRC not attached Punjab Govt. experience not attached Free sale certificate not attached Medical devices registration not attached	Rejected
26	PERIPHERAL BALLOON (MONORAIL) - ALL SIZES	T.N.A Sample not provided Punjab Govt. experience not attached Free sale certificate not attached Medical devices registration not attached	Sample provided Punjab Govt. experience not attached Free sale certificate attached Medical devices registration not attached	Rejected
27	PERIPHERAL STENTS (SELF EXPANDABLE/ BALLOON EXPANADABLE) - ALL SIZES	T.N.A Sample not provided Punjab Govt. experience not attached Free sale certificate not attached Medical devices registration not attached	Sample provided Free sale certificate attached Medical devices registration attached Punjab Govt. experience not attached	Rejected
31	PTCA BALLOON MONORAIL NON- COMPLIANT-ALL SIZES	T.N.A Free sale certificate not attached	Free sale certificate attached	Accepted
32	PTCA BALLOON MONORAIL (SEMI COMPLIANT) - ALL SIZES	T.N.A Free sale certificate not attached	Free sale certificate attached	Accepted

9. M/s Medtronic Pakistan Private Limited


Item #	Item Name	TAC Observations	GC Observation	Remarks
5	CLOT ASPIRATION CATHETER	T.N.A Medical Devices registration not attached	Medical Devices registration attached	Accepted
12	DIAGNOSTIC CATHETER ALL SIZES & ALL TYPES FDA APPROVED	T.N.A Stiff catheter	Observation raised by TAC is still holds good	Rejected
14	DRUG ELUTING BALLOON ALL SIZES	T.N.A All length not available	Observation raised by TAC is still holds good	Rejected
17	GUIDE WIRE 150-160 CM STANDARD LENGTH 0.035" JTIP	T.N.A Not according to specification 145cm quoted	Observation raised by TAC is still holds good	Rejected


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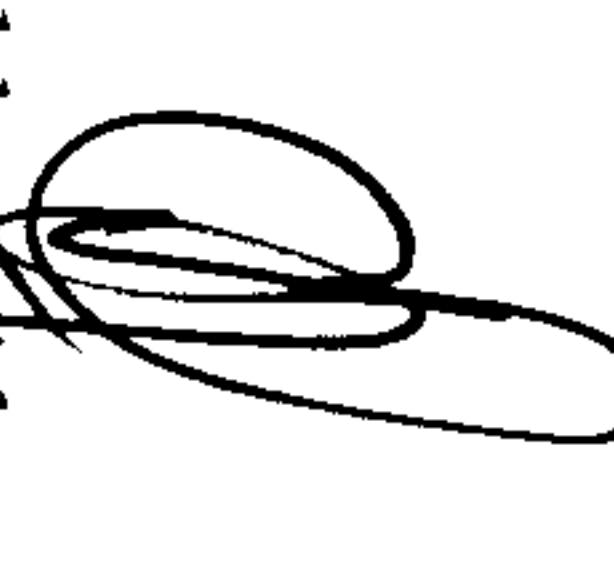
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19	GUIDING CATHETER ALL SIZES & ALL TYPES	T.N.A Stiff catheter	Observation raised by TAC still holds good	Rejected
31	PTCA BALLOON MONORAIL NON-COMPLIANT-ALL SIZES	T.N.A DRC not attached	DRC attached	Accepted
32	PTCA BALLOON MONORAIL (SEMI COMPLIANT) - ALL SIZES	T.N.A DRC not attached	DRC not attached	Rejected


Mrs. Ayesha Nasrullah,
Pharmacist,
FIC, Faisalabad.


Mr. Zaman Iftikhar,
BME Engineer,
FIC, Faisalabad.


Dr. Shahbaz Ahmed,
Associate Prof. of Cardiac Surgery,
FIC, Faisalabad.


Dr. Shahid Abbas,
Associate Prof. of Cardiology,
FIC, Faisalabad.


Dr. Muhammad Nadeem Akhtar,
Medical Superintendent,
FIC, Faisalabad.