



No.F.4-3/2023-MD (M-55)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad the 8th March, 2023

Subject:- **ENLISTMENT/REGISTRATION OF MEDICAL DEVICES FOR LOCAL MANUFACTURE – DEFERRED CASES (SUBMISSION OF DEFICIENT INFORMATION/DOCUMENTS THEREOF)**

The applications of following applicants were placed before Medical Device Board (MDB) in its 55th meeting held on 16st February, 2023 and Board deferred these applications being deficient of the information/documents as specified in last column (IV) of the Table below:

Sr. No.	Name & Address of Establishment	Name of Medical Devices With Size	Decision
I	II	III	IV
1.	M/s Kohinoor Industries, 160/B and 161/B, Small Industries Estate, Sahiwal. [ELM No. 0046]	LEADER LINT ABSORB Absorbent Cotton Lint (non-sterile) Class: A Shelf-life: 3 years Sizes: 25, 50, 100, 200, 400, 500 & 1000 grams Fee Challan No. 7833422520 Rs. 5000/-	Deferred for provision of following shortcomings: 1. Form-6 corrections required 2. Source of raw materials not provided 3. Stability studies not provided 4. Proposed MRP not provided 5. Details of manufacturing & QC processes not provided 6. Sample of labels and its packaging not provided
2.	M/s Kohinoor Industries, 160/B and 161/B, Small Industries Estate, Sahiwal. [ELM No. 0046]	PRIME BAND Absorbent Gauze BPC (Gauze BP-13 Light) Class: A Shelf-life: 3 years Sizes: OT Gauze Warped (Sterile & non Sterile):	Deferred for provision of following shortcomings: 1. Form-6 corrections required. 2. Source of raw materials not provided. 3. Stability studies not provided. 4. Proposed MRP not provided. 5. Details of manufacturing & QC processes not provided.


		<p>5cm x 5cm (4ply)(8ply)(12ply) Radio pack each 7.5cm x 7.5cm (4ply)(8ply)(12ply) Radio pack each 10cm x 10cm (4ply)(8ply)(12ply) Radio pack each 10cm x 20cm (4ply)(8ply)(12ply)</p> <p>Radio pack each Rolls: 1Mx1M, 1Mx2.5M, 1Mx10M, 1Mx20M, 1Mx30M, 1Mx40M, 1Mx50M, 1Mx90M, 1Mx100M.</p> <p>Fee Challan No. 1936704 Rs. 5000/-</p>	6. Sample of labels and its packaging not provided.
3.	<p>M/s Kohinoor Industries, 160/B and 161/B, Small Industries Estate, Sahiwal.</p> <p>[ELM No. 0046]</p>	<p>MEDI TULLE (Tulle Gras Dressing) 0.5% Chlorhexidine Acetate</p> <p>Non-sterile</p> <p>Class: A</p> <p>Shelf-life: 3 years</p> <p>Sizes: 10cmx10cm, 10cmx15cm, 15cmx15cm, 20cmx20cm, 10cmx100cm, 15cmx100cm, 15cmx150cm</p> <p>Fee Challan No. 1915069 Rs. 5000/-</p>	<p>Deferred for provision of following shortcomings:</p> <ol style="list-style-type: none"> 1. Form-6 corrections required. 2. Source of raw materials not provided. 3. Stability studies not provided. 4. Proposed MRP not provided. 5. Details of manufacturing & QC processes not provided. 6. Sample of labels and its packaging not provided.
4.	<p>M/s Kohinoor Industries, 160/B and 161/B, Small Industries Estate, Sahiwal.</p> <p>[ELM No. 0046]</p> <p>-173-</p>	<p>KETONOR TULLE Chitosan 100%</p> <p>Class: A</p> <p>Shelf-life: 3 years</p> <p>Sizes: 2cm x 2cm, 5cm x 5cm, 8cm x 8cm, 10cm x 12cm</p> <p>Fee Challan No. 2108218 Rs. 5000/-</p>	<p>Deferred for provision of following shortcomings:</p> <ol style="list-style-type: none"> 1. Form-6 corrections required. 2. Source of raw materials not provided. 3. Stability studies not provided. 4. Proposed MRP not provided. 5. Details of manufacturing & QC processes not provided. 6. Sample of labels and its packaging not provided.

5.	<p>M/s Kohinoor Industries, 160/B and 161/B, Small Industries Estate, Sahiwal.</p> <p>[ELM No. 0046]</p> <p>-175-</p>	<p>MEDISEPT TULLE Sulphadiazine 1% USP (Sterile)</p> <p>Class: A</p> <p>Shelf-life: 3 years</p> <p>Sizes: 10cm x 10cm (tulle) 10cm x 30cm (tulle) 10cm x 40cm (tulle) 10cm x 1m (roll) 10cm x 2m (roll) 15cm x 20cm (tulle) 15cm x 1.5m (roll) 15cm x 15cm (tulle)</p> <p>Fee Challan No. 2108219 Rs. 5,000/-</p>	<p>Deferred for provision of following shortcomings:</p> <ol style="list-style-type: none"> 1. Form-6 corrections required 2. Source of raw materials not provided 3. Stability studies not provided 4. Proposed MRP not provided 5. Sample of labels and its packaging not provided
6.	<p>M/s Kohinoor Industries, 160/B and 161/B, Small Industries Estate, Sahiwal.</p> <p>[ELM No. 0046]</p> <p>-101-</p>	<p>K-CIFIN Paraffin Gauze BP</p> <p>Class: A</p> <p>Shelf-life: 3 years</p> <p>Sizes: (Tin & Roll Pack) 10cm x 10cm 15cm x 15cm 20cm x 20cm 10cm x 100cm 15cm x 150cm</p> <p>Fee Challan No. 98106634443, Rs. 5000/-</p>	<p>Deferred for provision of following shortcomings:</p> <ol style="list-style-type: none"> 1. Form-6 corrections required. 2. Source of raw materials not provided. 3. Stability studies not provided. 4. Proposed MRP not provided. 5. Details of manufacturing & QC processes not provided. 6. Sample of labels and its packaging not provided.
7.	<p>M/s Al-Badar Manufacturing (Pvt) Ltd, Plot No.193/3, Road No.7, Industrial Estate Gadoon Amazai, District Swabi (ELM-0029)</p>	<p>ZINDAGI Disposable Syringe with needle 1ml & 10ml</p> <p>Class B</p> <p>Shelf life: 05 Years Fee Challan No. 2046546 Rs. 30000/-</p>	<p>Deferred for provision of following:</p> <ol style="list-style-type: none"> 1. Source of raw materials not provided 2. Stability studies not provided 3. Proposed MRP not provided 4. Details of manufacturing & QC processes not provided 5. Fee challan to be appropriated with Rs. 20000/- fee in favor of said product



8.	M/s Al-Badar Manufacturing (Pvt) Ltd, Plot No.193/3, Road No.7, Industrial Estate Gadoon Amazai, District Swabi (ELM-0029)	ZINDAGI Hypodermic Disposable Needles 16G, 18G, 21G, 22G, 23G, 24G, 26G, 27G Class B Shelf Life: 05 Years Fee Challan No. 91939870 Rs. 20,000/-	Deferred for provision of following documents: 1. Source of raw materials not provided 2. Stability studies not provided 3. Proposed MRP not provided 4. Details of manufacturing & QC processes not provided
9.	M/s Al-Badar Manufacturing (Pvt) Ltd, Plot No.193/3, Road No.7, Industrial Estate Gadoon Amazai, District Swabi (ELM-0029)	ZINDAGI Disposable Syringe with needle 20ml, 50ml, 60ml Class B Shelf life: 05 Years Fee Challan No. 1043773834 Rs. 20,000/-	Deferred for provision of following documents: 1. Source of raw materials not provided. 2. Stability studies not provided. 3. Proposed MRP not provided. 4. Details of manufacturing & QC processes not provided. 5. Sample of labels and its packaging not provided.
10.	M/s Injection System (Pvt) Ltd, Plot No.271, main road, Industrial Estate, Gadown Amazai, District Swabi, KPK (ELM-0034)	BIOSAFE Disposable Syringe with needle 20ml, 50ml, 60ml 16G, 18G, 21G, 22G, 23G, 24G Class B Shelf life: 05 Years Fee Challan No. 523901125988 Rs. 20,000/-	Deferred for provision of following documents: 1. Source of raw materials not provided 2. Stability studies not provided 3. Proposed MRP not provided 4. Details of manufacturing & QC processes not provided 5. Sample of labels and its packaging not provided

2. It is requested to furnish the requisite information/documents within 20 days after uploading of this letter on official website of DRAP.


08/03/2023

(BABAR KHAN)
Additional Director (MDMC)/
Secretary MDB