DRAFT MINUTES OF 297th MEETING OF CENTRAL LICENSING BOARD HELD ON 2nd MAY, 2024

297th meeting of the Central Licensing Board (CLB) was held on 2nd May, 2024 in the Committee Room, Ground Floor, NCLB, Drug Regulatory Authority of Pakistan (DRAP) National Institute of Health (NIH), Chak Shahzad, Islamabad. Dr. Muhammad Akhtar Abbas Khan, Director (Licensing), Drug Regulatory Authority of Pakistan, Islamabad Chaired the meeting. Following members attended the meeting: -

S.No	Name & Designation	Status
1.	Mr. Babar Khan Additional. Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
2.	Mr. Azher Jamal Saleemi, Chief Drugs Controller, Government of Punjab, Lahore	Member
3.	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Government of Khyber Pakhtunkhwa	Member
4.	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Baluchistan, Quetta	Member
5.	Mr. Abdul Hafeez Tunio, Chief Inspector of Drugs, Government of Sindh, Karachi (participated through zoom link)	Member
6.	Mr. Abid Ali, Deputy Draftsman, Ministry of Law & Justice Division, Islamabad	Member
7.	Ms Mahvash Ansari, Additional; Director, representative of QALT division, DRAP	Member

Mr. Babar Khan, Additional Director/Secretary Licensing Board presented the agenda before the Board. Ms Umme Laila Deputy Director (Lic.), Mr. Mubashir Iqbal, Deputy Director (Lic), Mr. Yaqoob Kakar, Assistant Director (Lic), Ms. Zunaira Faryad, Assistant Director (Lic) assisted the Secretary, Central Licensing Board in presenting the agenda. Mr. Kamran Anwar PCDA, Dr. Tahir Azam, PPMA, Mr Ehtisham Ul Haq, PPMA and Mr. Nadeem Alamgir, Pharma Bureau attended the meeting as observers.

Item-I **CONFIRMATION OF THE MINUTES OF 296th MEETING**

All members of the Central Licensing Board (CLB) formally confirmed and signed the minutes of 296th meeting of the Central Licensing Board (CLB) held on 2nd April, 2024.

Item-II: **GRANT OF NEW DRUG MANUFACTURING LICENSE.**

The respective panel of experts for grant of new Drug Manufacturing Licenses have forwarded following cases. The same are placed before the Board for its consideration/decision please.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1	M/s Steris Pharmaceuticals, Plot No. 09, Near Nova Synpac, Hattar Private Industrial Estate, Haripur, KPK. *(Evaluator: - Muhammad Yaqoob (AD-Lic)*	24-04-2024	Good	1. Mr. Muhammad Younas Khattak, Chief Drug Inspector, Peshawar. 2. Mr. Atiq ul Bari, Additional Director, DRAP, Peshawar. 3. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
	QC In-charge	Mrs. Sheher Bano D/o Syed Nasim Haider (B-Pharm) CNIC No.37406-15284667-6.		
	Production In-charge	Mr. Shahzada Abdul Salam S/o Sher Afzal Khan (B-Pharm) CNIC No.54400-3401992-5.		
	Management as per partnership deed	1. Mr. Sher Ali Baz Khan S/o Sardaraz khan 2. Mr. Sartaj Khan S/o Sher Bhadur Khan 3. Mr. Umar Ayaz S/o Sardaraz		
	Recommendations of the Panel: - As per manufacturing / testing equipment installed in the production, quality control & microbiology lab, utilities compliance status of the firm, the panel unanimously recommends the grant of DML by way of formulation to M/s. Steris Pharmaceuticals, Plot No. 09, Near Nova Synpac, Hattar Private Industrial Estate, Haripur, KPK. **Sections** 1. Tablet Section (General) 2. Capsule Section (General)			

3. Quality Control Lab/ Microbiology
4. R&D Section
5. Warehouse (RMS, PMS&FGS)

The firm submitted the following management as per the partnership deed at the time of site verification.

1. Mr. Sher Ali Baz Khan S/o Sardaraz khan
2. Mr. Sartaj Khan S/o Sher Bhadur Khan
3. Mr. Bakht Zada S/o Muhammad Usman
4. Mr. Umar Ayaz S/o Sardaraz

Now the firm has requested to change the management as follows.

1. Mr. Sher Ali Baz Khan S/o Sardaraz khan
2. Mr. Sartaj Khan S/o Sher Bhadur Khan
3. Mr. Umar Ayaz S/o Sardaraz

The firm has provided the following documents:

- Previous Partnership Deed
- Revised Partnership Deed
- NOC of the previous/outgoing management
- Previous Form-H issued on 02-10-2020 from Registrar of Firm.
- Revised Form-H issued on 30-08-2021 from Registrar of Firm.

Decision of the Central Licensing Board in 297th meeting:

The Board considered the recommendations of the panel of experts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Steris Pharmaceuticals, Plot No. 09, Near Nova Synpac, Hattar Private Industrial Estate, Haripur, KPK for the following sections;

1. Tablet Section (General)
2. Capsule Section (General)
3. Quality Control Lab/ Microbiology
4. R&D Section
5. Store (RMS, PMS&FGS)

Based on change of management with registrar of the firm, the Board considered and accepted for record the change of management of M/s Steris Pharmaceuticals, Plot No. 09, Near Nova Synpac, Hattar Private Industrial Estate, Haripur, KPK as under.

1. Mr. Sher Ali Baz Khan S/o Sardaraz khan
2. Mr. Sartaj Khan S/o Sher Bhadur Khan

	3. Mr. Umar Ayaz S/o Sardaraz
4.	

Item- III: **GRANT OF REGULARIZATION / REVISION/AMENDMENTS ETC.**

The respective panel of experts for grant of additional sections has forwarded following cases. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Hoechst Pakistan Ltd. (Formerly M/s Sanofi-Aventis Pakistan Ltd.,) Plot No.23, Sector 22, Korangi Industrial Area, Karachi). DML No.000007 (Formulation) *Evaluator: - Mubashir Iqbal (DD-Lic)* i. Tablet General Section - Revised.	26-03-2024	Good	1. Mr. Abdur Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Dr. Shoib Ahmed, Area FID, DRAP, Karachi. 3. Mr. Abdul Waheed, Assistant Director (I&E), DRAP, Karachi.
	M/s Sanofi-Aventis Pakistan Ltd., was inspected as per the instruction contained in letter no. F.2-4/2000-Lic (Vol-II) dated 11th March, 2024. During the targeted inspection the panel was informed that existing compression rooms are re-designed by surrendering their Dry Syrup Section. Now the firm has converted these rooms into two compression rooms annexed under Tablet (General) area. The newly section were found built as per approved design. The HVAC system was found operational. Separate dedicated HVAC units are provided in both rooms. The firm installed adequate equipment like compression machines, de-duster, and metal detectors in the manufacturing room. Based on the are inspected facilities, available and amenities, people met, documents reviewed and considering the finding of inspection the panel recommends the Approval for Grant of Additional Tablet Compression Section (General) of the firm. **Decision of the Central Licensing Board in 297th meeting:** The Board considered the recommendations of the panel of experts and approved the grant following revised sections in the name of M/s Hoechst Pakistan Ltd., Plot No.23, Sector 22, Korangi Industrial Area, Karachi under DML No. 000007 (Formulation) for following sections.			

	Tablet Section (General) Revised* *Revised means not a new or additional section

Item-IV: **GRANT OF RENEWAL / REGULARIZATION OF LOP OF DRUG MANUFACTURING LICENSES.**

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses and regularization. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1.	M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A, S.I.T.E., Super Highway, Karachi. **DML No. 000746 (Formulation)** **Period:** Commencing on 27-08-22 ending on 26-08-2027. Evaluator:- Mubashir Iqbal (DD-Lic)	09-04-2024	**Good**	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Sinsh. 2. Mr. Abdur Rasool Shaikh, Additional Director, DRAP, Karachi. 3. Mrs, Sanam Kausar Jahan, Assistant Director, DRAP, Karachi
	QC In-charge	Syed Khalid Nizam S/o Syed Nizam ul Haq (M.Sc Chemistry) CNIC No.42101-8486183-7.		
	Production In-charge	Mr. Muhammad Mudassir Hussain S/o Latafat Hussain (B-Pharm) CNIC No.42101-2143038-9.		
	Recommendations of the panel: *"*M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A, S.I.T.E., Super Highway, Karachi was inspected and visited in detail on 09-04-2024 in compliance to the directions contained in DRAP, Islamabad letter No.F.2-6/2013-Lic (Vol-I) dated 29th March, 2024. In connection with renewal of DML. The panel inspected all the manufacturing sections, stores and QC Lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities, machineries and equipment's as required under the guidelines. Necessary documents relating to QC/QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and noted an optimal level of compliance. 2. As the firm has been granted limited drug registration in each section which are also not viable for the manufacturer to market. Hence very limited manufacturing activities had been carried out during the last five years or during its inception and entire calculation			

and recommendations have been made on available/provided data. It is strongly recommended that their pending registration applications may kindly be considered on priority basis.

3. Keeping in view of the above, people met, documents reviewed and attitude of the management towards continuous improvement, the panel is of the opinion to recommend the grant of renewal of their DML No. 000746 (By way of Formulation) for the following sections commencing from 27-08-2022: -

Tablet (General)	Capsule (General)	Capsule (Cephalosporin)
Dry Powder Suspension (Cephalosporin)	Cream/Ointment (General)	**********

Decision of the Central Licensing Board in 297th meeting

The Board considered the recommendations of the panel of experts and approved the grant of renewal of DML No. 000746 by way of Formulation in the name of M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A, S.I.T.E., Super Highway, Karachion for the period commencing on 27-08-22 ending on 26-08-2027for the following sections subject to verification of equipment:

Tablet (General)	Capsule (General)	Capsule (Cephalosporin)
Dry Powder Suspension (Cephalosporin)	Cream/Ointment (General)	**********

2.	M/s Asian Continental (Pvt) Ltd., D/32, S.I.T.E., Super Highway, Karachi. **DML No. 000643 (Formulation)** **Period:** Commencing on 24-12-2023 ending on 23-12-2028. Evaluator:- Mubashir Iqbal (DD-Lic)	18-04-2024	Good	1. Mr. Abdul Hafeez Tunio, Chief Drug Inspector, Sinsh. 2. Mr. Abdur Rasool Shaikh, Additional Director, DRAP, Karachi. 3. Mrs, Sanam Kausar Jahan, Assistant Director, DRAP, Karachi
	QC In-charge	Mr. Fakhir Khaleeq Usmani S/o Muhammad Khaleeq Usmani (M.Sc Chemistry) CNIC No.61101-1990388-7.		
	Production In-charge	Mr. Kamran Awan S/o Shah Jahan Awan (B-Pharm)		
	Recommendations of the panel:			

1. **AsianContinental (Pvt.) Ltd**: D-32, SITE II Super Highway Karachi was inspected and visited in detail on 18-04-2024 in compliance to the directions contained in DRAP Islamabad Letter No.F.2-6/2013-Lic (Vol-I) dated 29th March, 2024 in connection with renewal of DML. The panel inspected all the manufacturing sections, stores and QC Lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities., machineries and equipment's as required under the guidelines. Necessary documents relating to QC/QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and noted an optimal level of compliance.
2. Keeping in view of the above, people met, documents reviewed and attitude of the management towards continuous improvements, the panel is of the opinion to **recommend the grant of renewal of their DML No.000643 (By way of Formulation)** for the following sectionssubject to verification of equipment::

S#	Section	S#	Section
1.	Tablet (General) Section	2.	Capsule (General) Section
3.	Oral Liquid (General) Section	4.	Dry Powder Suspension (General-Antibiotic) Section
5.	Liquid Ampoule (General) Section	6.	Quality Control Laboratory
7.	Warehouse	8.	Packing Material Warehouse

Decision of the Central Licensing Board in 297thmeeting

The Board considered the recommendations of the panel of experts and approved the grant of renewal of DML No. 000643 by way of Formulation in the name of M/s Asian Continental (Pvt) Ltd., D/32, S.I.T.E., Super Highway, Karachi for the period commencing on 24-12-2023 ending on 23-12-2028 for the following sections subject to verification of equipment;

S#	Section	S#	Section
1.	Tablet (General) Section	2.	Capsule (General) Section
3.	Oral Liquid (General) Section	4.	Dry Powder Suspension (General-Antibiotic) Section
5.	Liquid Ampoule (General) Section	6.	Quality Control Laboratory
7.	Warehouse	8.	Packing Material Warehouse

3.	M/s Regent Laboratories, Plot No.C-20, S.I.T.E., Super Highway, Karachi. DML No. 000506	**22-04-2024**	**Good**	1. Mr. Abdur Rasool Shaikh, Additional Director, DRAP, Karachi. 2. Mr. Sajjad Ahmed Abbasi, Deputy

	(Formulation) Period: Commencing on 26-10-2022 ending on 25-10-2028. Evaluator:- Mubashir Iqbal (DD-Lic)			Director, CDL, Karachi. 3. Mrs, Sanam Kausar Jahan, Assistant Director, DRAP, Karachi
	QC In-charge	Ms. Zakia Bibi D/o Abdul Samad Khan (M.Sc Chemistry) CNIC No.42201-0381513-2.		
	Production In-charge	Ms. Zahida Khatoon D/o Abrar ul Haque (B-Pharm) CNIC No.42101-1506817-4.		

Recommendations of the panel:

1. As per directions of DRAP Islamabad vide Letter No.F.2-24/85-Lic (Vol-IV) dated 03rd May, 2023 the constituted panel member inspected the premises of M/s Regent Laboratories, Plot No.C-20, S.I.T.E., Super Highway, Karachi on 22/04/2024 for grant of renewal of DML No.000506 (formulation). During opening meeting their Site Master File, lay out design, HVAC design and QMS were discussed at length and found an appropriate level of compliance. Instant BMR, documents and SOPSs were also reviewed in detail. Overall an optimal level of compliance was noted.
2. Keeping in view of the above, people met, documents reviewed and attitude of the management towards continuous improvements, the panel is of the opinion to **recommend the grant of renewal of their DML No.000506 (By way of Formulation)** for the next five years for the following sections:

GROUND FLOOR	
Veterinary Powder (General)	Veterinary Liquid (General)
Veterinary Vitamins (General)	Capsule (Penicillin)
Dry Powder Suspension (Penicillin)	Tablet (Psychotropic)
Capsule (Psychotropic)	Tablet (Hormone)
Capsule (Cephalosporin)	Dry Powder Suspension (Cephalosporin)
Tablet (Antibiotic)	Dry Powder Suspension (Antibiotic)
Capsule (Antibiotic)	Tablet (General)
Capsule (General)	Liquid Syrup (General)
Sachet (General)	
FIRST FLOOR	
Cream / Ointment (General)	Cream / Ointment (Steroidal)
Cream / Ointment (General/Antibiotic)	Liquid (General) External Preparation
Quality Control Lab	Stores

	<u>Decision of the Central Licensing Board in 297th meeting</u> The Board observed that the firm is involved in manufacturing of diverse and specialized nature of products including Penicillin, Hormones, Cephalosporin and antibiotics requiring segregation and dedication. The Board deferred the grant of renewal of DML No. 000506 and advised the Licensing division to review the LOP and place the case in forthcoming meeting.

Miscellaneous Cases:

Case No1. **NO OBJECTION CERTIFICATE FOR IMPORT OF MACHINERY/EQUIPMENT IN LIGHT OF 'PROMOTION AND GROWTH OF ACTIVE PHARMACEUTICAL INGREDIENT (API) INDUSTRY IN PAKISTAN POLICY', TO BE USED BY APIs MANUFACTURERS.**

Evaluator: Muhammad Abdullah AD Lic

1. The promotion and growth of the API industry in Pakistan require a comprehensive strategy encompassing short-term incentives to jumpstart the sector and long-term measures to sustain its development. By implementing targeted policies and fostering collaboration between the public and private sectors, Pakistan can emerge as a competitive player in the global API market while ensuring the availability of affordable and high-quality medicines for its population.

2. The Drug Regulatory Authority of Pakistan (DRAP) since its establishment is striving hard to facilitate both the general public and the Pharmaceutical manufacturers.

3. Policy regarding "Promotion and growth of API industry is approved by the Federal Cabinet and is notified by DRAP on 2nd March 2022 for creating self-reliance in the country by encouraging manufacturing of API by way of basic/semi-basic manufacturing and the policy is reproduced as under;

   "No.F.1-2/2022-CEO-DRAP: - In pursuance of the Federal Cabinet's decision in Case No. 79/05/2022 dated 15 February 2022, the Drug Regulatory Authority of Pakistan is pleased to notify the 'Promotion and Growth of Active Pharmaceutical Ingredient (API) Industry in Pakistan Policy', as follows: -

   Introduction

   Advanced and efficient technologies are needed for Active Pharmaceutical Ingredients (APIs) production to gain a competitive edge. Pakistan's API industry is in its initial phases and requires policies that promote its expansion. Currently, 23 pharmaceutical manufacturers possess the license to manufacture APl out of which 05 have the license for the basic manufacturing. 39 APIs are currently licensed for production by way of basic manufacturing whereas 117 APIs are licensed for production by way of semi-basic. These firms produce approximately 15% of API while the remaining 85% is being imported. Among locally produced bulk drug substances (APIs), national demand of 16 APIs is met and the most of national leading brands are using the afore-mentioned local APIs in their products.

   Global API market is currently over 180 billion USD and projected over 250 billion by 2024. Owing to its great potential and attaining self-reliance, it is desirable to invest in this sector. However, Investors shy away from setting up manufacturing plants due to complex nature of manufacturing processes, substantial cost of R&D involved, readily available APIs from international market and lack of incentivization.

There are numerous raw materials in the form of chemicals, starting materials and intermediates that are required for API manufacturing. The synthesis process of APIs might need multi-step complex chemistry utilizing a range of processing technologies and therefore, specialized equipment.

Due to its lucrative nature, many countries are investing in promotion and growth of their API industry. For this purpose, Governments of China, India, and Bangladesh have taken the lead to incentivize this industry for boosting its potential. For creating self-reliance in the country by encouraging manufacture of pharmaceutical raw materials by way of basic/ semi-basic manufacture, following short and long-term incentives to the existing and prospective industry are proposed:

A. Short-Term Incentives to API manufacturers

1. ***Reduction is suggested in custom duty on those starting & intermediate materials, chemicals, and machinery items by Tariff Policy Board for five years which are used in basic & semi-basic manufacturing but are not locally manufactured, and de not fall under current list of items having zero percent custom duty. Initially, a list of specific items will be referred by DRAP. However, due to dynamic nature of this list, DRAP may consider addition or deletion after approval of its Central Licensing Board (CLB) as and when needed.***

2. Any reduction in the import prices (dumping prices), of the materials manufactured in Pakistan, by the foreign suppliers should immediately be supported through levy of Anti-dumping Duty. The M/o NHS, R&C/ DRAP, after fulfilment of criteria of availability and quality, will forward the specific items to Tarif Policy Board for imposition of regulatory duty as and when it deems appropriate.

3. API manufacturers can avail financing facilities already available under 'Export Finance Scheme (EFS)' and 'Long-Term Finance Scheme (LTFF)' provided by State Bank of Pakistan.

4. Allowing API manufactures to retain export earnings to the tune of 15% of FOB value of their export's proceeds same as already allowed by Ministry of Finance for pharmaceutical sector.

5. The tariff structure of APIs will be reviewed by the Tariff Policy Board, on the recommendation of Ministry of National Health Services, Regulations and Coordination, as and when the production starts, on case-to-case basis.

6. DRAP will establish a cell for guidance to applicants/ investors, and to coordinate with relevant ministries on timely completion of requisites for issuance of licenses and registrations applied to it on a fast-track basis.

7. Establishing linkages between academia and basic /semi-basic API manufacturers for funding of related research projects from Higher Education Commission (HEC)/ Pakistan Science Foundation/ DRAP CRF/ International Donor Agencies.

B. Long-Term Incentives to API manufactures

1. Establishment of API Mega Parks with all the required facilities including but not limited to common wastage and effluent treatment plants, power houses, distillation plants and environmental control.

2. Ministry of Industries & Production shall develop a policy to incentivize Naphta Cracking Plant for promoting basic chemical and pharmaceutical industry.

4. In light of above policy, a dedicated API manufacturing Facilitation Cell in Licensing Division, DRAP was established for guidance to applicants/ investorsand applications related to API manufacturing are being disposed of accordingly.

5. A firm, M/s Zenith Hi-Chem Industries, Lahore (License in process) submitted an application for issuance of NOC for import of reduced customs duty (5%) plant, machinery & equipment for pharmaceutical manufacturers for following equipment used in the manufacturing of API;

S.#	Equipment
1	Model: 3000l ss316l reaction tank 3 sets
2	Model: 6000l ss316l dissolution reaction tank and crystallization reaction tank 4 se
3	Model: 1000l ss316l storage tank (vacuum) 3 set.
4	Model: 3000l ss316l storage tank (vacuum) 2 set,
5	12m2 ss316l storage condenser 4 set
6	16m2 ss316l condenser 3 set.
7	Model: 4000l ss316l reaction tank 2 set
8	Ae3000l ms glass lined reactor 4 sets
9	Ae6300l ms glass lined reactor 4 sets
10	Jb-650 turbine type cyclone-separating pukse dust collection crushing set 2 sets.
11	Zks-5 vacuum feed machine 2sets.
12	Jb-650 turbine type cyclone-separating pukse dust collection crushing set 2sets.
13	Zks-5 vacuum feed machine 2sets.
14	Jb-20mini efficient pulvirizer 1 set.
15	Zks-3 vacuum feed machine 2sets.
16	Jb-550 knife crusher with three sets of screens 6 mesh.10 mesh,20 mesh/set
18	Jb-300 rotarygranulator with one set of screen 1set.

19	50l glasslined reactor with double mechanical seal and inverter 2 sets.
20	Gfg-150 fluid bed dryer 3 sets
21	Boiler 1 set
22	Metal detector 3 sets.
23	Solid liquid separator 4 sets.

6. Another firm M/s. Humayun Chemical Industries (Pvt) Ltd, Lahore submitted an application for issuance of NOC for import of reduced customs duty (5%) plant, machinery & equipment for pharmaceutical manufacturers for following equipment used in the manufacturing of API;

List of Equipment in Cephalosporin derivatives Plant							
Sr. #	Name of Equipment	Equip Num	Capacity	Qty	Load	MOC	Working Pressure
1	Batch Reactor	C.R-01	3000 Ltr	1	7.5kw	SS-316L	-
2	Batch Reactor	C.R-02	5000 Ltr	1	11kw	SS-316L	-
3	Batch Reactor	C.R-03	5000 Ltr	1	11kw	SS-316L	-
4	Batch Reactor	C.R-04	5000 Ltr	1	11kw	SS-316L	-
5	Batch Reactor	C.R-05	7000 Ltr	1	11kw	SS-316L	-
6	Metering Tank	C.MT5-01,2,3	500 Ltr	3	_	SS-316L	-
8	Storage Tank	C.ST10-01	10000 Ltr	2	_	SS-304	-
9	Centrifuge	C.CF-01,02,03	300 Ltr	2	11kw	SS-316L	-
10	Rota Cone vacuum Dryer	C.RVD-01	1000 kgs	1	3kw	SS-316L/304	-
11	JB-20 Mini-efficient Pulverizer	C.PR-01	40-100kgs/hr	1	20kw	SS-316L/304	-
12	JB-350 Knife Crusher	C.KC-01	30-250kg/hr	1	7.5kw	SS-316L/304	-
13	GK-200 Dry Granulator Machine	C.COM-01	150-200kg/hr	1	11.2kw	SS-316L/304	-
14	JB-800 Sifting Machine One layer two outlets	C.SF-O1	50-500kgs/hr	1	0.55kw	SS-316L/304	-
15	JB-500 W-type mixer	C.MX-01	500L	1	3kw	SS-316L/304	-
16	Metal Detector (IMD-IIS-P100).	C.MD-02	IIS-P100L	1	-	SS-316L/304	-
17	Chiller with All	C.CH-01	40 Ton	1	26kw	-	-

	accessories						
18	Once Through Steam Boiler	C.BL-01	1-ton	1	-	-	-
List of Equipment in Penicillin derivatives Plant							
Sr. #	Name of Equipment	Equip Num	Capacity	Qty	Load	MOC	Working Pressure
1	Batch Reactor	PR-01	3000 Ltr	1	7.5kw	SS-316L	-
2	Batch Reactor	PR-02	6000 Ltr	1	11kw	SS-316L	-
3	Batch Reactor	PR-03	6000 Ltr	1	11kw	SS-316L	-
4	Batch Reactor	PR-04	6000 Ltr	1	11kw	SS-316L	-
5	Metering Tank	P.MT5-01,2,3	500 Ltr	3	-	SS-316L	-
7	Storage Tank	P.ST10-01	10000 Ltr	2	-	SS 304	-
7	Centrifuge	P.CF-01,02,03	300 Ltr	3	11kw	SS-316L	-
8	Fluid Bed Dryer	P.FBD-01	200 kgs	1	30Kw	SS-316L/304	-
9	JB-20 Mini-efficient Pulverizer	P.PR-01	40-100kgs/hr	1	20kw	SS-316L/304	-
10	ZKS-3 Vacuum Feeding Machine	P.VF-01	1200kg/hr	1	3kw	SS-316L/304	-
11	JB-350 Knife Crusher	P.KC-01	30-250kg/hr	1	7.5kw	SS-316L/304	-
12	JB-200 Dry Granulator Machine	P.COM-01	150-200kg/hr	1	17kw	SS-316L/304	-
13	JB-800 Sifting Machine One layer two outlets	P.SF-O1	50-500kgs/hr	1	0.55kw	SS-316L/304	-
14	JB-1000 W-type mixer	P.MX-01	1000L	1	4kw	SS-316L/304	-
15	ZKS-5 Vacuum Feeding Machine	P.VF-02	3000kg/hr	1	5.5kw	SS-316L/304	-
16	Metal Detector (IMD-IIS-6040)	P.MD-01	IIS-6040L	1	-	SS-316L/304	-
17	Metal Detector (IMD-IIS-P100).	P.MD-02	IIS-P100L	1	-	SS-316L/304	-
18	Chiller with All accessories	P.CH-01	40 Ton	1	26kw	-	-
20	Once Through Steam Boiler	P.BL-01	2 Ton	1	-	-	-

7. It is further submitted that as per approved SOP the licensed pharmaceuticals apply on firm's letter head signed by CEO / Director in the light of DRAP Authority Decision in its

116th Meeting for grant of NOC for import of machinery/equipment used in their **licensed premises** under heading 38 of the amended 5th Schedule of the Customs Act, 1969, along with following documents:

1) Section approval letter approved by CLB along with Approval letter of layout plan of the section where machinery to be installed.
2) Invoice of Machine/Equipment being imported.
3) Picture of imported Machine/Equipment.
4) Previous installation report of the machine imported by the firm verified by the Area Federal inspector of Drugs.
5) The scientific reason / justification for import of the machine.
6) Notarized Undertaking on Stamp Paper issued in the name of the firm/company or signatory & signed by the MD/CEO) of the firm/company containing following contents:
    i. Name, Model, Quantity of Machine/Equipment to be imported.
    ii. Name of section in which imported machinery/equipment is to be installed.
    iii. Total Cost of machinery as on Invoice of the machine / equipment to be imported.
    iv. Following Clauses in the light of the decision of DRAP Authority.;
        a. The machine(s) will be imported for their own use as per spirit of heading of 38 of the amended 5th schedule of the Customs Act 1969.
        b. The conditions specified in amended 5th schedule of the Customs Act 1969 shall be abide by.
        c. In case of any violation, firm will be responsible.

The Instant requests of the M/s Zenith Hi-Chem Industries, Shairf Complex-Manga Road, Link Islampura, Lahore and M/s. Humayun Chemical Industries (Pvt) Ltd, Lahore fall under the point no. 1 of short term incentives of the policy as mentioned above and submitted for consideration of the Board, please.

Decision of the Central Licensing Board in 297th meeting:

Central Licensing Board deliberated the request of M/s Zenith Hi-Chem Industries, Shairf Complex-Manga Road, Link Islampura, Lahore and M/s. Humayun Chemical Industries (Pvt) Ltd, Lahore, under process of establishment/ licening, in pursuance of the clause A (1) of Notification No.F.1-2/2022-CEO-DRAP 2nd March 2022 narrated as below:

"Reduction is suggested in custom duty on those starting & intermediate materials, chemicals, and machinery items by Tariff Policy Board for five years which are used in basic & semi-basic manufacturing but are not locally manufactured, and de not fall under current list of items having zero percent custom duty. Initially, a list of specific items will be referred by DRAP.

However, due to dynamic nature of this list, DRAP may consider addition or deletion after approval of its Central Licensing Board (CLB) as and when needed."

The Board recommended reduction in custom duty on the list of machinery as follows and decided to forward to DRAP for consideration and onward submission to Tariff Policy Board, FBR for further necessary action as per law.

Sr.	HS Code	Name of Equipment	MOC
1.	8479.8290	Reaction Tank	SS-316L
2.	8479.8290	Dissolution Reaction Tank	SS-316L
3.	8479.8290	Crystallization Reaction Tank Storage Tank	SS-316L
4.	8479.8290	Storage Condenser	SS-316L
5.	8479.8290	Condenser	SS-316L
6.	8419.8990	Glass lined Reactor	
7.	8479.8290	Turbine Type Cyclone-Separating Pulverizer Dust Collection Crushing Set	SS-316L
8.	8479.8290	Vacuum Feeding Machine	SS-316L
9.	8479.8290	Mini-Efficient Pulverizer	SS-316L
10.	8479.8290	Knife Crusher	SS-316L
11.	8479.8290	Rotary Granulator	SS-316L
12.	8419.3900	Fluid Bed Dryer	SS-316L
13.	8402.1990	Boiler	
14.	8543.7090	Metal Detector	
15.	8421.1900	Solid Liquid Separator	SS-316L
16.	8419.8990	Batch Reactor	SS-316L
17.	8419.8990	Metering Tank	SS-316L
18.	8421.1900	Centrifuge	SS-316L
19.	8419.3900	Rota Cone Vacuum Dryer	SS-316L
20.	8438.9090	Dry Granulator Machine	SS-316L
21.	8479.8290	Sifting Machine	SS-316L
22.	8479.8290	W-Type Mixer	SS-316L
23.	8418.6990	Chiller	
24.	8402.1990	Once Through Steam Boiler	
25.	8402.1990	Once Through Steam Boiler.	

The Board further decided that due to dynamic nature of the above list, DRAP may consider addition or deletion after approval by Central Licensing Board (CLB) as and when needed. The Board also approve following SOP subject to approval by DRAP Authority in its upcoming meeting;

Following documents shall be submitted along application;

1) The firm (under process of licensing) whose LOP is approved by Licensing division and construction of firm is complete shall apply for pre import permit.
2) Invoice of Machine/Equipment being imported.
3) Picture of imported Machine/Equipment.
4) In case of replacement of previous machine/equipment, previous installation report of the machine imported by the firm verified by the area Federal inspector of Drugs.

5) The scientific reason / justification for import of the machine.
6) Notarized Undertaking on Stamp Paper issued in the name of the firm/company or signatory & signed by the MD/CEO) of the firm/company containing following contents:
    i. HS Code of the equipment/machinery
    ii. Name, Model, Quantity of Machine/Equipment to be imported.
    iii. Name of section in which imported machinery/equipment is to be installed.
    iv. Total Cost of machinery as on Invoice of the machine / equipment to be imported.
    v. Following Clauses in the light of the decision of DRAP Authority.;
        d. The machine(s) will be imported for their own use as per spirit of heading of 38 of the amended 5th schedule of the Customs Act 1969.
        e. The conditions specified in amended 5th schedule of the Customs Act 1969 shall abide by.
        f. In case of any violation, firm will be responsible.

The Board also authorize its chairman to make any necessary amendments/corrections in the specification of above approved machinery/equipment if required by the Tariff Policy Board.

Case No. 2. **SITE VERIFICATION REQUEST OF M/S PINNACLE BIOTECH (PVT.) LTD. KARACHI.**

The Division of Licensing DRAP has received an application for site verification of M/s Pinnacle Biotech (Pvt.) Ltd. Karachi at Plot no. WH-01-20-A7-A8_Bin Qasim Industrial Park Karachi, Pakistan for the establishment of Pharmaceutical & Nutraceutical Plant. The plot size as per submitted documents is 10 Acres. The firm has provided following documents:

i. Fee
ii. Article of Association
iii. Memorandum of Association
iv. Form-A and Form-29
v. CNICs of Directors
vi. Certificate of Incorporation
vii. Land Documents with copy of Site Map

The firm was asked which biotech products they intend to manufacture as the name of the firm could be misleading. As per memorandum of association, they intend to do businesses of non-pharma products, nutraceuticals etc. as well. The firm replied as follows:

"Thank you for your query regarding the biotech products that our firm intends to manufacture and clarification required in our Principal Line of Business.

As per our Memorandum of Association, the firm is primarily focused on pharma products. However,

we understand the need for clarification and would like to provide further information.

While biotech products are indeed part of our future expansion plans, our immediate focus is on establishing a specialized plant for Cephalosporin products.

Moreover, for a comprehensive understanding of our firm's business activities, we would like to draw your attention to the SECP Attested Form-A and Form 29. These documents clearly indicate that Pinnacle Biotech (Pvt.) Ltd.'s principal line of business is in the field of Pharmaceuticals. I have attached the SECP Attested Form-A for your reference and clearance."

The matter is placed before the Central Licensing Board for deliberation and directions.

Decision of the Central Licensing Board in 297th meeting:

Board members discussed the request of the firm and decided that "biotech" title cannot be approved for a company that does not manufacture biotech products. The Board advised the firm to change the firm's name before site verification.