

**SEEPZ SPECIAL ECONOMIC ZONE
ANDHERI (EAST), MUMBAI.**

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AGENDA FOR

**MEETING OF THE APPROVAL COMMITTEE FOR
SECTOR SPECIFIC SPECIAL ECONOMIC ZONE FOR
MANUFACTURING OF PHARMACEUTICAL PRODUCTS
AT AURANGABAD OF M/S. WOCKHARDT
INFRASTRUCTURE DEVELOPMENT LTD.-SEZ**

DATE : 29.02.2024

TIME : 12.00 P.M.

**MEETING OF THE APPROVAL COMMITTEE FOR SECTOR
SPECIFIC SPECIAL ECONOMIC ZONE FOR MANUFACTURING
OF PHARMACEUTICAL PRODUCTS AT AURANGAD, UNDER THE
CHAIRMANSHIP OF DEVELOPMENT COMMISSIONER, SEEPZ-
SEZ ON 29.02.2024**

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Agenda Item No.	Subject
Agenda Item No. 01 :-	Confirmation of the Minutes of the meeting held on 26.08.2022
Agenda Item No. 02 :-	Request for approval for broad banding of products submitted by M/s. Wockhardt Ltd. Unit 2

Minutes of the 29th Meeting of the Approval Committee held under the Chairmanship of Zonal Development Commissioner SEEPZ-SEZ, Mumbai for Sector Specific Special Economic Zone for Pharmaceutical in Wockhardt Infrastructure Development Ltd.-SEZ, Aurangabad, held on 26.08.2022 via video conferencing.

1	Name of the SEZ	Wockhardt Infrastructure Development Ltd.-SEZ
2	Sector	Pharmaceutical
3	Meeting No.	29 th
4	Date	26.08.2022

Members present

Sr	Name and Designation (S/Shri.)	Department
1	Smt. Mital S. Hiremath Joint Development Commissioner	Pune Cluster-SEZ, Pune
2	Smt. Pradnya R. Gholap DCIT (TDS) Pune	Nominee of Income Tax, Pune
3	Dr. Dileeraj Dabhole Dy. DGFT	Nominee of DGFT, Pune
4	Smt. Sunita Jagtap Superintendent	Nominee of Customs, Pune

Special Invitee

Sr	Name and Designation	Department
1	Shri V. U Golhait Specified Officer	Wockhardt Infrastructure Development Ltd-SEZ, Aurangabad, SEZ-Pune Cluster

Agenda Item No.01: Confirmation of Minutes of the 28th meeting held on 26.07.2022

After deliberation, the Committee confirmed the minutes of the 28th Approval Committee meeting held on 26.07.2022.

Agenda Item No.02: Application submitted by M/s. Wockhardt Ltd. Unit 1 for broad branding of products

After deliberation, Committee approved the proposal of the Unit for broad banding of products, as detailed below, required for authorized operations, in terms of Rule 19(2) of SEZ Rules, 2006.

(i) Approved authorized operation/activity:

Pharmaceutical product for Human Consumption (Tablets / Capsule) in Vials / Ampules / Bottles etc.

(ii) Proposed (additional) authorized operation/manufacturing activity
for Broad Banding:

Sr. No.	Product	HSN Code	SKU	Brands	Qty /volume projected in 5 years (2024-2027)
1	Human Insulin	30043110	Vial, Cartridge, Re-usable Pen, Disposable Pen (assembled with drug filled cartridges)	Wosulin, Wozulim, Newsulin, Consegna, Glysolin, Winsulin or other trademarks as per availability in different countries	7000
2	Insulin Glargine	30043110	Vial, Cartridge, Re-usable Pen, Disposable Pen (assembled with drug filled cartridges)	Glaritus, Valvey, Glarzen or other trademarks as per availability in different countries	9700
3	Insulin Aspart - Regular	30043110	Vial, Cartridge, Re-usable Pen, Disposable Pen (assembled with drug filled cartridges)	As per availability in different countries	1700
4	Insulin Aspart - 30/70	30043110	Vial, Cartridge, Re-usable Pen, Disposable Pen (assembled with drug filled cartridges)	As per availability in different countries	350 (in last 3 yrs)

5	Insulin Lispro - Regular	30043110	Vial, Cartridge, Re-usable Pen, Disposable Pen (assembled with drug filled cartridges)	As per availability in different countries	250 (in last 1 yrs)
6	Insulin Lispro - 25/75	30043110	Vial, Cartridge, Re-usable Pen, Disposable Pen (assembled with drug filled cartridges)	As per availability in different countries	50 (in last 1 yrs)

The unit had submitted application for renewal of their LOA on 18.05.2022 and the projection for the additional products, as detailed below, were considered by the unit in their renewal application. The projections were monitoring during the LOA renewal and approved in the 28th UAC meeting held on 26.07.2022

Revised projections:

	2022-23	2023-24	2024-25	2025-26	2026-27	(Rs. in lakhs) Total
FOB value of export	5280	15030	20050	25040	35040	100440
FE Outgo	3283	9561	13695	18519	24957	70015
NFE	1997	5469	6355	6521	10083	30425

(iii) Investment / Capital Goods / Raw Material

(Rs. In lakhs)

	Projections for the next block period of 5 yrs.
Capital Goods	
Indigenous	4,200.90
Imported	16,803.60
Total	21,004.50
Raw Material	
Indigenous	122,52.62
Imported	36,757.87

TOTAL	49,010.50
Input Services	
Indigenous	700.33
Imported	15.00
TOTAL	715.33
Employment	
Male	450
Female	50
TOTAL	500

Meeting ended with a vote of thanks to the Chair.

Signed by Shri. Shyam
Jagannathan
Date: 07-09-2022 06:44:17
(Shyam Jagannathan, IAS)
Reason: Approved
Chairman-cum- Development
Commissioner

GOVT. OF INDIA,
OFFICE OF THE ZONAL DEVELOPMENT COMMISSIONER,
SEEPZ – SEZ (PUNE CLUSTER),
ANDHERI (EAST), MUMBAI

AGENDA NOTE FOR CONSIDERATION OF THE APPROVAL COMMITTEE

a. Proposal: -

Proposal of M/s. Wockhardt Ltd Unit-2. located at, MIDC Aurangabad -SEZ, for approval of broad banding of Additional new product for manufacturing without any revision in projection.

b. Specific Issue on which decision of Approval Committee is required:

Approval of the Committee for broad banding of Additional new product for manufacturing without any revision in projection, in terms of Rule 19(2) of SEZ Rules, 2006.

Broad banding of additional items of product in existing LOA as authorized operations as detailed below:

Current Approved Operations	Proposed additional authorized Operations
Manufacturing pharmaceuticals product i.e., Nasal and Inhaler dosage Form for Human Usage.	<ul style="list-style-type: none"> • Human Insulin • Insulin Glargine <p>ITC-HS Code 30043110 For both the above Products</p>

Reason for Broad Banding:

The unit has submitted that they are not in a position to commence their operation, as the products and the manufacturing facility needs to be registered in foreign countries before it can export any product. Such registration, which involves the Inspection of the plant too by the Food and Drug Administration officials of the Importing countries (USFDA) and it takes normally 18 to 24 months. The unit has been regularly applying for inspection to USFDA Authority and paying fee for the same and due to pandemic situation in the past, the Inspection was delayed and hence the unit is yet to commence its operations and has been seeking extension of LOA since the expiry of LOA w.e.f 24.02.2014 due to above reasons.

Further, the Unit has now submitted their application for approval of 11th Extension for the validity of LOA vide their letter dated 22.01.2024 and it is in process.

M/s Wockhardt Ltd. is committed to make the unit operational therefore they have submitted the application for broad banding for adding new product i.e. Human Insulin in their existing LOA to make the unit operational in due course in terms of

Rule 19(2) of SEZ Rules, 2006. The applicant has Unit-1 for Human Insulin product. The approval of BOA for extension and UAC approval for broad banding will facilitate the utilization of existing facility for manufacturing of Human Insulin for export.

List of products is as below:

Sr. No	Product	SKU	Brands
1	Human Insulin	Vial, Cartridge-usable pen, Disposable Pen (assembled with drug filled with cartridges)	Wosulin, Wozulim, Newsulin, Consegna, Glysolin, Winsulin, or other trademarks as per availability in different countries.
2	Insulin Glargine	Vial, Cartridge, Re-usable pen, Disposable Pen (assembled with drug filled with cartridges)	Glaritus, Valvey, Glarzen or other trademarks as per availability in different countries.

Unit has submitted the Quantity/ volume forecast over the period of 5 years.

		Quantity is in '000's				
Product	SKU	FY 25	FY 26	FY 27	FY 28	FY 29
Human Insulin	Vial, Cartridge-usable pen, Disposable Pen (assembled with drug filled with cartridges)	1000	1500	2000	2500	3000
Insulin Glargine	Vial, Cartridge, Re-usable pen, Disposable Pen (assembled with drug filled with cartridges)	1100	1950	2800	3850	4800

c. Relevant Provision:

- As per 1st proviso to Rule No.19(2) of SEZ Rules, 2006
"the Approval Committee may also approve proposals for broad banding, diversification, enhancement of capacity of production, change in the items of manufacturing or service capacity, if it meets the requirements of rule 18".

d. Other Information: -

- M/s. Wockhardt Ltd, Unit-2. is an existing SEZ Unit with, LOA No. SEEPZ-SEZ/NEWSEZ/WOCKHARDT-AURBD/02/LOA-02/2012-13/2402 Dated 25.02.2013.
- Unit has also submitted that the aforesaid product shall be covered in their existing approved projections in their LOA.

e) ADC's Observation: -

Approval Committee may kindly consider the proposal of the unit for Broad Banding of Additional new product without any revision in projection, in terms of Rule19(2) of SEZ Rules, 2006.
