ISO 9001:2015 Certified

भारत सरकार

केन्द्रीय औषध मानक नियन्त्रण संगठन पश्चिम खण्ड स्वास्थ्य सेवाओं का महानिदेषालय, स्वास्थ्य एवं परिवार कल्याण मंत्रालय चौथा तल,झोनल एफ.डी.ए. भवन, जी.एम.एस.डी. कम्पाउंड, विलासी रोड, मुम्बई सेन्ट्रल, मुम्बई—400 008.



GOVERNMENT OF INDIA

CENTRAL DRUGS STANDARD CONTROL ORGANISATION WEST ZONE

Directorate General of Health Services Ministry of Health and Family Welfare

4TH Floor, Zonal FDA Bhawan, GMSD Compound, Bellasis Rd, Mumbai Central, Mumbai-400 008.

Tel: 022-23002215 /23002279

Fax: 022-23002271 Email: wzmumbai@cdsco.nic.in

CDSCO

(By Email)

Ref: 7-6 / Pendency Status/WZ/2022/3528

Date:

30 SEP 2022

To
The Drugs Controller General (India)
Directorate General of Health Services,
FDA Bhavan, Kotla Road,
New Delhi – 110002.

Subject: Uploading of Pendency on CDSCO website with respect of application received at Zonal Office of CDSCO-WZ for the month of September - 2022 – regarding.

Sir,

With reference to office Memorandum No. DCGI/MISC/2014 (110), dated 19/08/2014, 08/09/2014 and 02/12/2014 for the subject cited above, please find enclosed herewith detail status of pendency with reason for uploading on website of CDSCO in prescribed format for compilation as mentioned in Annexure – I to IX

Yours faithfully,

For DEPUTY DRUGS CONTROLLER (NDIA) CDSCO, WEST ZONE, MUMBAI

Encl: As above

ANNEXURE – 1

i) Applications of issue of WHO GMP (COPP) pending more than 28 days at CDSCO, WZ

Total Applications received in the Month of September 2022= (16)

Inward No. (available with Applicant)	Date of Receipt	Reason & Remarks	
NIL	NIL	NIL	

ii) Applications for grant / renewal of vaccine / biological product license pending more than 30 days at CDSCO, WZ

Total Applications received in the Month of September 2022= (02)

Inward No. (available with applicant)	Date of Receipt	Reason & Remarks	
NIL	NIL	NIL	

iii) Applications for grant / renewal of Blood Bank licenses pending more than 21 days at CDSCO, WZ

Total Applications received in the Month of September 2022= (14)

Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
NIL	NIL	NIL

iv) Applications for grant / renewal of license for Medical Devices pending more than 90 days at CDSCO, WZ(By online Sugam Portal)

Total Applications received in the Month of September 2022= (10)

File No. Date of Receip		Reason & Remarks of pendency
NIL	NIL	NIL

v) Applications for grant / renewal of license for Public Testing Laboratory pending more than 21 days at CDSCO, WZ

Total Applications received in the Month of September 2022= (NIL)

Inward No. (available with applicant)	Date of Receipt	Reason & Remarks	
NIL	NIL	NIL	

vi) Applications of BA/BE Centre pending more than 30 days at CDSCO, WZ

Total Applications received in the Month of September 2022= (NIL)

Inward No. (available with applicant)	Date of Receipt	Reason & Remarks
NIL	NIL	NIL

vii) Application for issue Export NOC (kits/Exhibit batches etc) and permission for dual use item pending more than 7 days at CDSCO ,WZ.

A) Export

Total Applications received in the Month of September 2022 = (04)

Sr. No.	Inward No. (available with applicant)	Date of receipt	Reason and remarks (Out ward No/ Date)
1	NA	NA	NA

B) Dual Use (By online Sugam Portal)

Applications received in the Month of September 2022 = (1385) (Approved applications – 1156, Query issued – 86, Under process – 140, Rejected – 03)

Sr. No	File No.	Date of receipt	Reason and remarks of pendency
1.	NIL	NIL	NIL

viii) Applications of endorsement of Additional products for WHO GMP (COPP) pending more than 28 days at CDSCO, WZ.

Total Applications received in the Month of September 2022= (01)

Inward No.	Date of Receipt	Reason & Remarks
(available with Applicant)		
Nil	Nil	Nil

ix) Applications of grant of Manufacturing license/ Loan manufacturing license pending more than 28 days at CDSCO, WZ.

Total Applications received in the Month of September 2022= (09)

Inward No. (available with Applicant)	Date of Receipt	Reason & Remarks
Nil	Nil	Nil