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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

COSCO

Ref: 7-6 / Pendency Status/WZ/2021/3571

Date: 26/02/2021

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 – 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,

(DR. RUBINA BOSE)

Rosen

DEPUTY DRUGS CONTROLLER (INDIA)
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 February 2021= (03)

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 February 2021= (01)

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 February 2021= (06)

Inward No. (available with applicant)	Date of Receipt	Reason & Remarks	
452	18.01.2021	Admin reason	
459	18.01.2021	Admin reason	

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 February 2021= (11)

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

 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 February 2021= (01)

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 February 2021= (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 February 2021= (Nil)

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 February 2021 = (827) (Approved applications – 728, Query issued – 39, Under process – 55, Rejected – 05)

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 February 2021= (Nil)

Inward No. (available with Applicant)	Date of Receipt	Reason & Remarks
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 February 2021= (05)

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