

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, New Delhi
Dated 30.10.2025

OFFICE ORDER

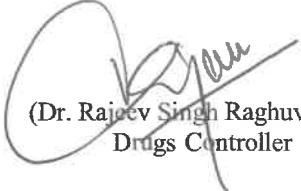
Subject: Delegation of powers to the officers of CDSCO under various rules of the Drugs and Cosmetics Act, 1940 – regarding.

In exercise of powers conferred under Drugs & Cosmetics Act 1940 and various Rules made thereunder, the following powers, under Drug Rules, 1945 and New Drugs and Clinical Trial Rules, 2019 as the case may be, are delegated to the respective Joint Drugs Controller (India) appointed by the Central Government in CDSCO :

Sl. No.	Rule	Delegation of powers to respective Joint Drugs Controller (India) to sign/issue the following items
1.	Drug Rules, 1945	Delegation of LA Powers: (i) Grant of license in Form-10/10A in respect of import license in respect of Drugs for Human use. Delegation of CLAA Powers: (i) Grant of License in Form 28E & Form 28F and renewal of License in Form 26I & Form 26J in respect of Blood Products and Umbilical Cord Blood Stem Cells.
2.	New Drugs and Clinical Trial Rules, 2019	Delegation of CLA Powers: (i) Additional/new site in Clinical Trial/Bioavailability and Bio-equivalence study covered under permissions issued in Form CT-04, CT-05, CT-06, CT-07 & CT-09. (ii) Examination and payment of compensations in case of SAEs related to Clinical Trials/ BA-BE study as per the rules.

3. With respect to Sl. No. 1 of the table, the respective JDC(I)s are appointed as “Central Licence Approving Authority” under Rule 2(b) of the Drugs Rules, 1945.

4. This issues with the approval of Competent Authority.


(Dr. Rajeev Singh Raghuvanshi)

Drugs Controller (India)

Copy to:

- 1) All JDC(I)/DDC(I)s
- 2) CDSCO website and e-office notice board

Copy for information to:

- 1) PSO to Secy. (H&FW)/DGHS
- 2) PPS to JS (NG)
- 3) Director (Drugs Regulation)