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Government of India

Directorate General of Health Services

Central Drugs Standard Control Organisation

FDA Bhawan, Kotla Road,
Near ITO, New Delhi – 110002

Date:

CIRCULAR

21 JUL 2026

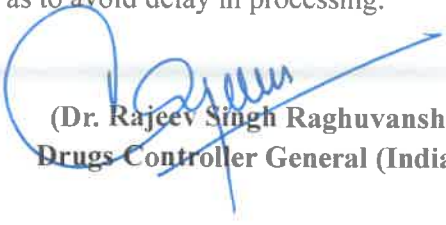
Subject: Clarification regarding submission of applications under Rule 4 of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025.

It has been observed that applications for compounding of offences under Rule 4 of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025 are being submitted before the Central Compounding Authority even in cases where the offence falls within the jurisdiction of the State Drug Control Administration.

In order to ensure uniform implementation of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025, the following clarification is issued for the information and guidance of all manufacturers, importers, distributors, licence holders and other stakeholders:

1. An application for compounding of an offence shall be submitted before the appropriate Compounding Authority having jurisdiction over the offence.
2. Where the sample has been drawn by a Drugs Inspector appointed by a State/UT's Government and the alleged offence falls within the jurisdiction of the State/UT Drugs Licensing Authority, the application for compounding shall be submitted to the concerned State/UT's Compounding Authority.
3. Where the sample has been drawn by a Drugs Inspector of CDSCO or the offence pertains to matters under the jurisdiction of the Central Licensing Authority, the application shall be submitted to the Central Compounding Authority.
4. The competent Compounding Authority shall be determined based on the authority that drew the sample. Where the sample is drawn by a CDSCO Drugs Inspector, the application shall lie before the Central Compounding Authority. Where the sample is drawn by a State/UT Drugs Inspector, the application shall lie before the respective State/UT Compounding Authority, in accordance with the provisions of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025.
5. Applications filed before an authority not having jurisdiction are liable to be returned or rejected, and the applicant may be advised to submit the application before the competent Compounding Authority having the requisite jurisdiction.

All stakeholders/Manufactures/Applicants are advised to ascertain the competent Compounding Authority before submitting an application under Rule 4 of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025, so as to avoid delay in processing.


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)