

Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India

Legal Cell Division

**Frequently Asked Questions (FAQs) on
Drugs and Cosmetics
(Compounding of Offences) Rules, 2025.**

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Central Drugs Standard Control Organization

Directorate General of Health Services,

Ministry of Health and Family Welfare, Government of India

FDA Bhavan, ITO, Kotla Road, New Delhi -110002

Email: dci@nic.in

Notice:

The replies to the FAQs are aimed only for creating public awareness about Drugs and Cosmetics (Compounding of Offences) Rules, 2025 and are not meant to be used for legal or professional purposes.

FAQs on Drugs and Cosmetics (Compounding of Offences) Rules, 2025

1. General Overview –

Q1. What are the Drugs and Cosmetics (Compounding of Offences) Rules, 2025?

Ans: These are rules notified under the Drugs and Cosmetics Act, 1940, providing a legal mechanism to compound (settle) certain offences without full court prosecution, subject to conditions. They lay out the procedure, authorities, forms, and conditions for compounding.

Q2. When did these rules come into effect?

Ans: They came into force on the date of their publication in the Official Gazette — 24th April 2025.

Q3. Under which legal provisions are these rules made?

Ans: They are made under clause (r) of sub-section (2) of section 33 read with section 32B of the Drugs and Cosmetics Act, 1940.

Q4. Are compounding of offences allowed under the Drugs and Cosmetics Act, 1940?

Ans: Yes. Under Section 32B of the Act, any offence punishable under clause (b) of sub-section (1) of section 13, clause (d) of section 27, clause ii of Section 27A, Section 28, and section 28A (Whether committed by a company or any officer therof, not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may either before or after the institution of any prosecution is compoundable by the Central Government or any State Government, or any officer authorized by them.

2. Definitions

Q5. Who is an “applicant”?

Ans: Any company or person engaged in manufacturing, import, sale, distribution, or other activities under the Drugs and Cosmetics Act and rules.

Q6. Who is the “compounding authority”?

Ans: An officer appointed by the Central or State Government (not below the rank of a reporting authority) authorized to process and decide on compounding applications. Compounding Authority [Additional Director General of Health Services notified vide S.O.No. 3551 (E) dated 1st August 2025.)

Q7. Who is the reporting authority under Drugs and Cosmetics (Compounding of Offences) Rules, 2025?

Ans: Reporting authority means the Licensing Authority or the Central Licensing Authority or the Central License Approving Authority appointed by the Central Government or the Licensing Authority appointed by State Government, as the case may be, under the Act and rules made thereunder, having jurisdiction over the place where an offence under the Act has been or alleged to have been committed.

Q8. Who can apply for the Compounding of Offences under Drugs and Cosmetics Act, 1940?

Ans: Any company or individual involved in manufacturing, import, sale, distribution, or any other activity covered under the provisions of the Act and Rules.

Q9. Who is the “reporting authority”?

Ans: The licensing authority (central or state) under the Act with jurisdiction over the place where the offence occurred.

3. Appointment of Compounding Authority (Rule 3)**Q10. Who can appoint a compounding authority?**

Ans: Both the Central Government and State Governments can appoint such authorities by notification in the Official Gazette.

4. Form and Manner of Application (Rule 4)-**Q11. When can an application for compounding be made?**

Ans: Either before or after institution of prosecution.

Q12. Who must make the application?

Ans: The individual company or person involved in the activity related to the offence. Each entity must apply individually.

Q13. Which form should be used?

Ans: The application must be made in the prescribed Form appended to the rules 4 of Drugs and Cosmetics (Compounding or Offences) Rules, 2025.

Q14. How to apply for Compounding of Offences under Drugs and Cosmetics Act, 1940?

Ans: The applicant may, either before or after institution of prosecution, make an application in the prescribed Form under Rule 4 to the compounding authority along with relevant documents

Q15. What is the procedure of compounding of offence under these rules?

Ans:

1. On receipt of an application, the compounding authority calls for a report from the reporting authority.
2. The report shall be furnished within one month (or extended period).
3. The compounding authority may allow the application (specifying the compounding amount and grant immunity) or reject it.

5. Procedure for Compounding (Rule 5)-

Q16. What is the first step after submitting the application?

Ans: The compounding authority will request a factual report from the reporting authority.

Q17. How long does the reporting authority have to respond?

Ans: One month from receipt of communication, extendable by the compounding authority.

Q18. Can the compounding authority reject an application?

Ans: Yes, but only after giving the applicant an opportunity to be heard and recording the reasons in writing.

Q19. How is the compounding amount decided?

Ans: It is fixed by the compounding authority based on the case facts.

Q20. How long does the applicant have to pay the compounding amount?

Ans: Within 30 days of receiving the order.

Q21. Can the compounding amount be refunded?

Ans: No, except if the court rejects the grant of immunity from prosecution.

Q22. Is compounding a right of the applicant?

Ans: No, it is at the discretion of the compounding authority.

6. Immunity from Prosecution (Rule 6)

Q23. When can immunity be granted?

Ans: When the applicant has fully cooperated and made full, true disclosure of facts.

Q24. Who grants immunity?

Ans: The compounding authority, subject to conditions it deems fit.

7. Withdrawal of Immunity (Rule 7)

Q25. When is immunity automatically withdrawn?

Ans: If the applicant fails to pay the compounding amount within the stipulated time or fails to comply with any conditions attached to the immunity.

Q26. Can immunity be withdrawn later?

A: Yes, if it is found that the applicant concealed material particulars or gave false evidence during the compounding proceedings.

Q27. What happens after withdrawal of immunity?

Ans: The person can be prosecuted for the offence as if no immunity had been granted.

Q28. Can immunity from prosecution be withdrawn?

Ans:

1. Immunity is withdrawn if the applicant fails to pay the compounding amount or comply with conditions.
2. Immunity may also be withdrawn if the applicant concealed material facts or gave false evidence, and prosecution can then proceed as if immunity was never granted.

8. Form Requirements

Q29. What details are required in the form?

Ans: Applicant details, product details, licence details, manufacturing/import info, certificate of analysis, sample/test details, offence particulars, seizure details, facts of the case, previous offences, and other relevant case details. (Rule 4, under the Drugs and Cosmetic – Compounding of Offence) Rules, 2025.

Q30. Is there a declaration in the form?

Ans: Yes, the applicant must declare willingness to pay the compounding amount and acknowledge that compounding is not a right.

Q31. Can the applicant claim compounding as a right?

Ans: No, compounding is at the discretion of the compounding authority.

Q32. Does the Compounding Authority have power to grant immunity from prosecution?

Ans: Yes, if satisfied that the applicant has cooperated and made full, true disclosure, immunity may be granted subject to conditions.

Q33. How much time is given to the applicant to pay the compounding amount and furnish proof?

Ans: Within 30 days from the date of the compounding order. The amount is generally non-refundable except if the Court rejects grant of immunity.