

**Guidelines on Compounding of Offences under the Drugs and
Cosmetics Act, 1940 as per 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 & FAMILY WELFARE
GOVT. OF INDIA**

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1. PREFACE -

The Drugs and Cosmetics (Compounding of Offences) Rules, 2025 have been framed under the provisions of Section 32B read with Clause (r) of sub-section (2) of Section 33 of the Drugs and Cosmetics Act, 1940. These rules provide a legal framework for the compounding of certain offences under the Act by allowing companies or individuals to avoid prosecution, subject to conditions and the discretion of the Compounding Authority.

This guidance document has been prepared by the Central Drugs Standard Control Organization (CDSCO) to assist all stakeholders, including manufacturers, importers, distributors, and regulatory officers, in understanding and complying with the newly notified rules.

This document intends to provide clarity on the application procedure, roles of authorities, eligibility, powers of compounding authority, immunity provisions, and associated forms to promote transparency, uniformity, and ease of compliance.

2. INTRODUCTION -

The Drugs and Cosmetics Act, 1940, ensures the safety, efficacy, and quality of drugs, cosmetics, and medical devices in India. Traditionally, non-compliance under the Act could result in prosecution. However, recognizing the need to address minor and technical contraventions without overburdening the judicial system, Section 32B was introduced to allow for compounding of offences.

The Drugs and Cosmetics (Compounding of Offences) Rules, 2025, operationalize the compounding mechanism by prescribing detailed procedures, authorities involved, forms, and conditions for compounding. This mechanism is a significant step towards compliance-focused regulation and encourages self-correction by regulated entities.

The Union Health Ministry has appointed the Additional Director General of Health services dealing with the matters of Central Drugs Standard Control Organisation (CDSCO) as the compounding authority to deal with the compounding of offences under the recently amended Drugs and Cosmetics (Compounding of Offences) Rules, 2025. The Ministry of Health & Family Welfare (MoHFW) issued various notification General Statutory Rules & Statutory Orders.

a) Jan Vishwas Act Amendment Notification - 28th March, 2024 –

- Ministry of Health & Family Welfare (MoHFW) issued notification S.O. 1577(E).
- Amendments to the Drugs and Cosmetics Act, 1940 under the Jan Vishwas (Amendment of Provisions) Act, 2023 were notified.
- Effective date fixed as 31st December, 2024.

b) Draft Rules Published - 10th July, 2024 –

- MoHFW issued G.S.R. 374(E).
- Draft of Drugs and Cosmetics (Compounding of Offences) Rules, 2023 published.
- Objections/suggestions were invited within 45 days from the public after Gazette publication.

c) Final Rules Notified - 24th April, 2025 –

- MoHFW issued G.S.R. 259(E).
- Final Drugs and Cosmetics (Compounding of Offences) Rules, 2024 notified.
- Draft rules of July 2024 were finalized after considering public objections and suggestions.

d) Compounding Authority Appointed -1st August, 2025 –

- MoHFW issued S.O. 3551(E).

e) Additional Director General of Health Services (CDSCO) designated as the Compounding Authority.

- Authority empowered to exercise powers of Central Government regarding compounding of offences.
- Came into force on date of publication in Gazette.

3. APPLICABILITY-

CDSCO Head Office, Zonal, Subzonal office & Port office.

4. KEY DEFINITIONS-

- **Applicant:** Any company or person engaged in manufacturing, import, sale, distribution, or other activities under the Drugs and Cosmetics Act and rules.
- **Compounding Authority:** 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.
- **Reporting Authority:** 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.

5. FORM AND MANNER OF APPLICATION –

1. Stage of Application-

The applicant may file the application either before or after the institution of prosecution.

2. Authority to Apply -

The application shall be made to the compounding authority under Section 32-B of the Act.

3. Application Requirements-

The application must be: In the prescribed Form, and Accompanied by all relevant information and documents.

4. Who Can Apply-

The application for compounding shall be made individually by: A company, or A person involved in: Manufacturing, Import, Sale, Distribution Or any other activity covered under the Act and the rules made thereunder.

6. PROCEDURE FOR COMPOUNDING OF OFFENCES-

Procedure-

- 6.1 Whenever any application under Rule 4 of Drugs and Cosmetics (Compounding of Offences) Rules, 2025 in the prescribed form is received through physical mode along with an advance copy in email at raj.shree64@cghs.nic.in to the office of Compounding Authority, the e-file of the application is required to generate by the concerned department.
- 6.2 The compounding authority shall call for a report from reporting authority, under whose jurisdiction offence has been committed with reference to the particular furnished in the application.
- 6.3 The reporting authority within 05 days of receipt of application shall ask the report from the concerned zonal/sub-zonal/port office in whose jurisdiction the offence has been committed with reference to the particulars furnished in the compounding application.
- 6.4 The concerned head of the zonal/sub-zonal/port office shall forward their report within 10 days of receipt of application with reference to the particulars furnished in the compounding application.
- 6.5 The reporting authority shall forward his report to the compounding authority within one month of receipt of compounding application for the report or within such extended period as may be allowed by the compounding authority.
- 6.6 The compounding authority after taking into the account the content of the application may, by order either allow the application indicating the compounding amount and grant him immunity from prosecution in terms of rule 6 of Drugs and Cosmetics (Compounding of Offences) Rules, 2025 or reject the compounding of offence application.
- 6.7 The compounding authority shall afford the personal hearing before rejecting the compounding of offence application and the ground of rejection shall be mentioned in the order passed by the compounding authority.
- 6.8 The every order passed by the compounding authority shall be communicated to the applicant.
- 6.9 The applicant shall within the period of 30 days from the date of receipt of order of allowing the compounding of offence, pay the compounding amount as order to be paid by the compounding authority and shall furnish the proof of such payment to the compounding authority.
- 6.10 The compounding amount once paid on the order of compounding authority shall not be refundable except in cases where court reject grant of immunity from prosecution grant by the compounding authority.
- 6.11 The applicant cannot claim, as of right, that the offence to be compounding.
- 6.12 The compounding authority may grant Immunity from prosecution with such conditions as deemed fit for the offence with respect to the case covered by the Compounding of offence under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025. The immunity shall be grant if the compounding authority is satisfied that the applicant has cooperated in the proceeding and has made full and true disclosure of facts relating to the case.
- 6.13 The Immunity from prosecution in certain cases shall stand withdrawn, if person fails to pay sum of specified order of Compounding passed by the compounding authority.
- 6.14 The immunity granted to the applicant, may be withdrawn by the compounding authority, if satisfied that such applicant had, in the course of compounding proceedings, concealed any particulars, material or had given false evidence, and thereupon such person may be tried for the offence with respect to which immunity

has been granted or for any other offence that appears to have been committed by him in connection with the compounding proceedings and their upon the provision of the Act, shall apply as no such immunity has been granted.

7. IMMUNITY FROM PROSECUTION- POWER OF COMPOUNDING AUTHORITY TO GRANT IMMUNITY FROM PROSECUTION-

1. The compounding authority has the power to grant immunity from prosecution.
2. Immunity may be granted if the authority is satisfied that the applicant:
 - (a) Has cooperated in the proceedings before the authority, and
 - (b) Has made full and true disclosure of facts relating to the case.
3. Such immunity is granted with respect to the case covered by the compounding of offence.
4. The immunity may be granted subject to conditions as the compounding authority deems fit.

8. WITHDRAWAL OF IMMUNITY - FROM PROSECUTION IN CERTAIN CONDITIONS-

1. Automatic Withdrawal of Immunity-

- Immunity granted under Rule 6 shall stand withdrawn if the person:
 - a) Fails to pay the compounding amount specified in the order under Rule 5(3) within the prescribed time, or
 - b) Fails to comply with any conditions subject to which immunity was granted.
- In such cases, the provisions of the Act shall apply as if no immunity had been granted.

2. Withdrawal by Compounding Authority-

- Immunity may be withdrawn by the compounding authority at any time if it is satisfied that the person:
 - a) Concealed any particulars or material facts during compounding proceedings, or
 - b) Gave false evidence in such proceedings.
 - On such withdrawal, the person may be:
 - Tried for the original offence for which immunity was granted, or
 - Tried for any other offence connected with the compounding proceedings.
 - The provisions of the Act shall apply as if no immunity had been granted.

9. FORM FOR APPLICATION (SUMMARY) -

Details to be provided in the Form include:

- Applicant and contact details
- Product and licence details
- Details of offence, sample, seizure
- Whether prosecution has been initiated or contemplated
- History of previous offences
- Declaration and verification

10. AUTHORITIES INVOLVED –

Authority	Role
Compounding Authority	Compounding Authority [Additional Director General of Health Services as notified as CA by S.O. No. 3551(E) dated 01 st August 2025. The appointment of Compounding Authority vide O.M number-Z.18025/02/2018-Admin- I dated 23.10.2025.
Reporting Authority	Reporting Authority [CLAA/CLA appointed by the Central Government).
Applicant	Submits the application and complies with orders

FORM (See Rule 4)

APPLICATION FOR COMPOUNDING OF OFFENCES
(Under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025)

Sr. No.	Particulars	Details	Checklist (Yes / No / NA)
1	Full name and address of the applicant		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
2	Address for communication		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
3	Name and composition of the product		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
4	Manufacturing Licence / Import Licence / Registration Certificate details (including address, email, and contact details)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
5	Manufactured or Imported by		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
6	Marketed by, if any		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
7	Export or Import Code Number (if applicable)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
8	Certificate of Analysis of Manufacturer or NABL accredited laboratory (if any)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
9	Details of sample (if applicable)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
10	Date of sample drawn (Form 17 of Drugs Rules, 1945 / Form COS-10 of Cosmetics Rules, 2020 / Form MD-36 of Medical Device Rules, 2017)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
11	Date of test report received (Form 13 or Form 2 of Drugs Rules, 1945 / Form COS-14 or Form COS-21 of Cosmetics Rules, 2020 / Form MD-32 or Form MD-31 of Medical Device Rules, 2017)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
12	The contravention of provisions of the Drugs and Cosmetics Act, 1940, against which prosecution is instituted or contemplated		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
13	Date of seizure (if any)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
14	Brief facts of the case and particulars of the offence(s) charged		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA

15	Whether Show Cause Notice or Chargesheet issued		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
16	Whether this is the first offence under the Drugs and Cosmetics Act, 1940 (if not, provide details of previous cases)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
17	Whether any proceedings for the same offences are contemplated under any other law (if so, provide details)		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA

DECLARATION

1. I shall pay the compounding amount, as may be fixed by the compounding authority under the Rule..... of the Drugs and Cosmetics (Compounding of Offences) Rules, 2025 there under.

2. I understand that I cannot claim, as of right that the offences committed by me under the Act shall be compounded.

Name and Signature of the applicant

VERIFICATION

I,.....the son/daughter/wife of.....residing at.....do solemnly declare that I am making this application in my capacity as and I am competent to verify it.

That the contents of this application are true to the best of my knowledge and belief and no information relevant to the facts of the case has been suppressed. The documents accompanying the application are true copies of the originals and are duly attested by me.

Verified today the day of (month), (year) at

Name and Signature of the applicant

Process Flow Chart

1. Submission of Application

Applicant submits application under Rule 4 of Drugs and Cosmetics (Compounding of Offences) Rules, 2025 in the prescribed form through physical mode along with an advance copy in email at raj.shree64@cghs.nic.in to the office of Compounding Authority



2. Receipt of Application by the Compounding Authority

Application received by Compounding Authority office [O/o Add. Director General of Health Services, MoHFW, Government of India]. Generate e-file by supporting staff/division



3. Mark Application

E-file marked to Compounding Authority



4. Request Report

Compounding Authority calls report from Reporting Authority [DCG(I)]



5. Request from officer under whose jurisdiction offence has been committed:

Reporting Authority [DCG(I)] within 05 days of receipt of compounding application shall ask report w.r.t. facts mentioned in the compounding application from the concerned zonal/sub-zonal/port office



6. Report of concerned head of zonal/sub-zonal/port office

Concerned head of zonal/sub-zonal/port office within 10 days of receipt of compounding application shall forward their report w.r.t. facts mentioned in the compounding application.



7. Report of Reporting Authority:

Reporting Authority shall forward his report within 1 month or extended period as allowed by compounding authority from the date of receipt of receipt of application.



8. Compounding Authority Decision

Reviews application & report

Decision : → Allow Application or Reject Application



9. Allow Application

- Order indicating compounding amount
- Grant immunity under Rule 6
- Communicate order to applicant

- Applicant pays within 30 days & furnishes proof of payment (non-refundable)



10. Reject Application

- Personal hearing to applicant
- Grounds of rejection recorded
- Order communicated to applicant



11. Immunity Conditions

- May impose conditions
- Immunity if cooperation & full disclosure

Decision : - Concealment / false evidence →

Step 11

- Failure to pay amount → Step 10
- Otherwise → Immunity maintained



12. Withdrawal of Immunity

- Applicant may be tried for offence
- Act applies as if immunity was never granted