	TITLE		Division Name	Legal Cell
	Procedure for filing, processing, and finalizing applications for compounding of offences under Section 32B of the Drugs and Cosmetics Act, 1940.		Document No.	Legal Cell -GNL-000
			Revision No.	00
			Effective Date	
			Page No.	1 of 4

Prepared By		Approved By		Authorized By	
Name	Dr. Kailash Chander Malik	Name	A. Senkathir	Name	Dr. Rajeev Singh Raghuvanshi
Designation	ADC (I)	Designation	DDC (I)	Designation	DCG (I)
Sign		Sign		Sign	
Date	30.12.2025	Date	30/12/25	Date	01.01.2026

Control Status

CONTROLLED COPY

1.0 Purpose

To lay down a procedure for establishment of a standard approach for processing of applications under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025.

2.0 Scope

This document is applicable for processing of application for compounding of offences received under Section 32B of the Drugs and Cosmetics Act by the Compounding Authority.

3.0 Responsibility

3.1 Technical Data Associate/ Sr. Technical Data Associate/ Drugs Inspector shall be responsible for review of Compounding of offence application.

3.2 The ADC(I)/DDC(I)/JDC(I)/DCG(I) shall be responsible for timely forwarding of reporting authority report called by Compounding Authority.

4.0 Accountability

3.3 Compounding Authority [Additional Director General of Health Services notified vide S.O. No. 3551 (E) dated 1st August 2025.

3.4 Reporting Authority [Drugs Controller General (India) being the CLA/CLAA]

5.0 Procedure

5.1.1 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 by the office of Compounding Authority, the e-file of the application is required to generate by the concerned department.

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5.1.2 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.

5.1.3 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.

5.1.4 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.

5.1.5 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.

5.1.6 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.

5.1.7 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.

5.1.8 The every order passed by the compounding authority shall be communicated to the applicant.

5.1.9 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.

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5.1.10 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.

5.1.11 The applicant cannot claim, as of right, that the offence to be compounding.

5.1.12 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.

5.1.13 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.

5.1.14 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 being 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.

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8.0 Annexure / Format-

Annexure/Format No.	Title
Annexure-1 Legal Cell-GNL-000/F02-00	Application form as per rule 4
Annexure-II Legal Cell-GNL-000/F02-00	Compounding of offence process flow chart

8.0 References

Doc. No.	Title
1	Drugs and Cosmetics (Compounding of Offences) Rules, 2025

8.0 Abbreviation

Acronym	Full Form
CA	Compounding Authority [Additional Director General of Health Services as notified as CA by S.O. No. 3551(E) dated 01st August 2025.
RA	Reporting Authority [CLAA/CLA appointed by the Central Government)
QMS	Quality Management System
SOP	Standard Operating Procedure
CDSCO	Central Drugs Standard Control Organization
DCG(I)	Drugs Controller General (India)
JDC(I)	Joint Drugs Controller (India)
DDC(I)	Deputy Drugs Controller (India)
ADC(I)	Assistant Drugs Controller (India)
DI	Drugs Inspector
STDA	Sr. Technical Data Associate
TDA	Technical Data Associate
DEO	Data Entry Operator

9.0 Revision History

Revision No.	Reason(s) for Revision
00	New

Annexure-I- Application for Compounding of Offences
(Under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025)

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

FORM (See Rule 4)

Sr. No.	Particulars	Details	Checklist (Yes / No / NA)
1	Full name and address of the applicant		☐ Yes ☐ No ☐ NA
2	Address for communication		☐ Yes ☐ No ☐ NA
3	Name and composition of the product		☐ Yes ☐ No ☐ NA
4	Manufacturing Licence / Import Licence / Registration Certificate details (including address, email, and contact details)		☐ Yes ☐ No ☐ NA
5	Manufactured or Imported by		☐ Yes ☐ No ☐ NA
6	Marketed by, if any		☐ Yes ☐ No ☐ NA
7	Export or Import Code Number (if applicable)		☐ Yes ☐ No ☐ NA
8	Certificate of Analysis of Manufacturer or NABL accredited laboratory (if any)		☐ Yes ☐ No ☐ NA
9	Details of sample (if applicable)		☐ Yes ☐ No ☐ 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)		☐ Yes ☐ No ☐ 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)		☐ Yes ☐ No ☐ NA
12	The contravention of provisions of the Drugs and Cosmetics Act, 1940, against which prosecution is instituted or contemplated		☐ Yes ☐ No ☐ NA
13	Date of seizure (if any)		☐ Yes ☐ No ☐ NA
14	Brief facts of the case and particulars of the offence(s) charged		☐ Yes ☐ No ☐ NA
15	Whether Show Cause Notice or Chargesheet issued		☐ Yes ☐ No ☐ NA
16	Whether this is the first offence under the Drugs and Cosmetics Act, 1940 (if		☐ Yes ☐ No ☐ NA

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

	not, provide details of previous cases)		
17	Whether any proceedings for the same offences are contemplated under any other law (if so, provide details)		☐ Yes ☐ No ☐ NA

Declaration:

I hereby declare that the information provided above is true and correct to the best of my knowledge and belief. I undertake to provide any further information or documents as may be required by the Compounding Authority.

Place: _____

Date: _____

Signature of the Applicant: _____

Name (in block letters): _____

Designation & Seal (if applicable): _____

Annexure-II- Process flow chart

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

Process Flow Chart

1. Submission of Application
Applicant submits application under Rule 4 in prescribed format in physical copy along with advance copy through email at raj.shree64@cghs.nic.in by the office of Compounding Authority

⇩

2. Receipt of Application by the Compounding Authority
Application received by Compounding Authority office
[Office of Add. Director General of Health Services, MoHFW, Government of India]
Action: 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

⇩

Annexure-II- Process flow chart

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

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 grante