

MINISTRY OF HEALTH AND FAMILY WELFARE**(Department of Health and Family Welfare)****NOTIFICATION**

New Delhi, the 10th July, 2024

G.S.R. 374(E).— The following draft of the Drugs and Cosmetics (Compounding of Offences) Rules, 2023, which the Central Government proposes to make in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the gazette of India containing these draft rules are made available to the public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 434, C Wing, Nirman Bhawan, New Delhi – 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. **Short title and commencement.**—(1) These rules may be called the Drugs and Cosmetics (Compounding of Offences) Rules, 2023.
(2) They shall come into force on the date of their publication in the Official Gazette.
2. **Definitions.**—In these rules, unless the context otherwise requires,—
 - (a) "Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940);
 - (b) "applicant" means any company or other person
 - (c) "Compounding authority" means the authority appointed under rule 3 of these rules by central government or state government, as the case may be;
 - (d) "Form" means the Form appended to these rules;
 - (e) "Reporting authority" means the Licensing Authority or the Central Licensing Authority or the Central License Approving Authority appointed by 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 the offence under the Act has been or alleged to have been committed;
 - (f) "section" means a section of the Act; and
 - (g) Words and expressions used in these rules and not defined but defined in the Act shall have the respective meanings assigned to them in the Act.
3. **Power to effect these rules.**—(1) The Central Government may, for the purpose of these rules, by notification in the official gazette, appoint any person under these Rules, as compounding authority for the purpose of exercising powers and functions of the Central Government under these rules and for taking measures with respect to matters arisen from these rules.
(2) The State Government may, for the purpose of these rules, by notification in the official gazette, appoint any person under these rules, as compounding authority for the purpose of exercising such powers and functions of the State Government under these rules and for taking measures with respect to matters arisen from these rules.
4. **Form and manner of application.**—(1) An applicant may, either before or after institution of prosecution, make an application under section 32(B) of the Act in the Form-1 appended to these rules along with such relevant information and documents, to the compounding authority for compounding of the offence.
5. **Procedure for compounding.**—(1) On receipt of an application under rule 4, the compounding authority shall call for a report from the reporting authority, under whose jurisdiction offence has been committed, with reference to the particulars furnished in the application, or any other information, which may be considered relevant for examination of such application.
(2) Such report shall be furnished by the reporting authority within a period of one month or within such extended period as may be allowed by the compounding authority, from the date of receipt of communication from the compounding authority.
(3) The compounding authority after taking into account the contents of the said application may, by order, either allow the application indicating the compounding amount and grant him immunity from prosecution in terms of rule 6 or reject such application:
Provided that application shall not be rejected unless an opportunity has been given to the applicant of being heard and the grounds of such rejection are mentioned in such order.
(4) A copy of every order under sub-rule (3) shall be sent to the applicant.
(5) The applicant shall, within a period of thirty days from the date of receipt of order under sub-rule (3) allowing the compounding of offences, pay the compounding amount, as ordered to be paid by the compounding authority and shall furnish the proof of such payment to the compounding authority.
The compounding amount once paid shall not be refunded except in cases where the Court rejects grant of immunity from prosecution.
(6) The applicant cannot claim, as of right, that his offence shall be compounded.

6. **Power of Compounding authority to grant immunity from prosecution.**—The compounding authority, if satisfies that any person who has made the application for compounding of offence under these rules has co-operated in the proceedings before the authority and has made full and true disclosure of facts relating to the case, grant to such person, subject to such conditions as deemed fit to impose, immunity from prosecution for the offence under the Drugs and Cosmetics Act, 1940 with respect to the case covered by the compounding of offence.
7. **Withdrawal of Immunity from Prosecution in certain conditions.**— An immunity granted to a person under rule 6 shall stand withdrawn, if such person fails to pay any sum specified in the order of compounding passed by the Compounding authority, under sub-rule(3) of rule 5 within the time specified in such order or fails to comply with any other condition subject to which the immunity was granted and thereupon the provisions of the Drugs and Cosmetics Act, 1940 shall apply as if no such immunity had been granted.
2. An immunity granted to a person under sub-rule(1) above may, at anytime, be withdrawn by the Compounding authority, if satisfies that such person had, in the course of the compounding proceedings, concealed any particulars, material or had given false evidence, and there upon such person may be tried for the offence with respect to which immunity was granted or for any other offence that appears to have been committed by him in connection with the compounding proceedings and there upon the provisions of the Drugs and Cosmetics Act, 1940 shall apply as if no such immunity had been granted.

FORM-1

(See rule 4)

(Application for compounding of offences)

1. Full name and address of the applicant:
2. Address for communication:
3. Name and composition of the product:
4. Manufacturing or Import Licence details (including address, email and contact details):
5. Manufactured or Imported by:
6. Marketed by, if any:
7. Export or Import code No, if applicable:
8. Certificate of Analysis of Manufacturer or NABL lab, if any:
9. Details of Sample, if applicable:
 - a. Date of sample drawn (Form 17 of Drugs Rules, 1945):
 - b. Date of test report received in Form 13 or Form 2 of Drugs Rules, 1945, if applicable:
10. The contravention of the provisions of the Drugs and Cosmetics Act, 1940, against which prosecution is instituted or contemplated:
11. Date of Seizure, if any:
12. Brief facts of the case and particulars of the offence(s) charged:
13. Whether Show Cause Notice/Chargesheet issued:
14. Whether this is the first offence under the Drugs and Cosmetics Act, 1940, if not details of the previous cases:
15. Whether any proceedings for the same offences contemplated under any other law, if so the details thereof:

Name and Signature of the applicant

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, 2023 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

[F.No. X.11035/127/2023-DR]

RAJIV WADHAWAN, Advisor (Cost)