MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th February, 2025

G.S.R. 127(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 10(E), dated the 4th January, 2025, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of seven days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on 04th January, 2025;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government.

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), with the consideration that consultation with Drugs Technical Advisory Board shall be held as per the provisions of the said Act, the Central Government hereby makes the following rules, further to amend the Drugs (Amendment) Rules, 2023, namely:-

1. Short title and Commencement:- (1) These rules may be called the Drugs Amendment Rules, 2025.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs (Amendment) Rules, 2023, in rule 6, in the Table, in the entry against ‘Small and Medium manufacturers’, under column (2) after the words “Twelve months from the date of publication of these rules”, the following proviso shall be inserted, namely :-

“Provided that the small and medium manufacturers with turnover less than two hundred and fifty crores may seek extension of the timeline for implementation and for that purpose shall make an application to the Central Licence Approving Authority in Form ‘A’ annexed to this notification, within a period of three months from the date of publication of this notification, along with a plan of upgradation and for such manufacturers, the timeline for implementation shall be extended till 31st day of December, 2025”.

[F. No. X.11014/2/2017-DRS]

RAJIV WADHAWAN, Adviser (Cost)

English-only convenience copy prepared from the official CDSCO/Gazette G.S.R. 127(E), 11 February 2025.

FORM A

Application for seeking extension of compliance with Revised Good Manufacturing Practices (GMP) under Schedule-M of the Drugs Rules, 1945

Sl.No.	Item	Details
1.	Name and address of the manufacturer	
2	Turnover (year April, 2023-March, 2024)	
3	Details of the licence in all forms,- (i) Licence number (ii) Validity	
3	Sections held	
4	Whether holding World Health Organisation Good Manufacturing Practices (WHO-GMP)/Certificate of Pharmaceutical Product (CoPP), If yes, the validity of the certificate	
5	Details of gap analysis (section wise) (i) Plant, (ii) Equipment, (iii) Lab equipment (iv) HVAC system, (v) Utilities, (vi) Technical staff, (vii) Documentation (viii) Others	
6	Plan or strategy for compliance with the revised GMP (item wise as per the gap analysis at Sl. No. 5) Starting on or before 31.03.2025	
7.	Extension of time required for compliance (not beyond 31st day of December, 2025)	
8	Justification of the time required for compliance	

Undertaking

I undertake that I have carried out the gap analysis and propose to initiate upgradation within three months from the date of this application and comply with the revised Schedule-M requirements as per the plan submitted at Sl.no.6. above.

Date:

Place: Signature

(Director/Partner/Proprietor/Authorised Signatory)

Footnote : The Principal rules were published on the Official Gazette vide notification number G.S.R. 922(E), dated the 28th December, 2023.