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-Mar ch, 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.

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