Union Ministry of Health Proposes Amendments to Schedule M to Align Grade A Microbial Monitoring Requirements with WHO Guidelines

The Proposed Amendment to Strengthen Microbial Monitoring in Grade A Areas and Align Sterile Pharmaceutical Manufacturing Standards with WHO Guidelines

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Union Ministry of Health and Family Welfare has proposed amendments to Schedule M of the Drugs Rules, 1945, vide G.S.R. No. 953(E) dated 28 October, 2026, to revise the prescribed limits for microbial contamination in Grade A clean areas in accordance with the World Health Organization (WHO) Technical Report Series (TRS) No. 1044, Annexure 2, on Good Manufacturing Practices (GMP) for Sterile Pharmaceutical Products.

The proposed amendment aims to address the existing differences between the microbial contamination limits prescribed under Schedule M and the corresponding WHO requirements for Grade A areas, thereby bringing India's regulatory provisions in line with internationally recognised standards.

Grade A areas are critical zones in sterile pharmaceutical manufacturing, where exposed products, containers and sterilised components are handled. Maintaining stringent microbial control in these areas is essential to ensuring the quality and safety of sterile pharmaceutical products.

The proposed revision will harmonise the Revised Schedule M with WHO guidelines and further strengthen the regulatory framework governing sterile pharmaceutical manufacturing in the country. It also provides for treating any microbial growth detected in Grade A areas as a trigger for investigation, in accordance with WHO guidance.

The proposed amendment reflects the Government's commitment to strengthening quality standards in pharmaceutical manufacturing, aligning domestic regulatory requirements with international benchmarks and ensuring the quality and safety of pharmaceutical products.

Stakeholders and members of the public are invited to submit their objections and suggestions, if any, on the proposed amendment to the Under Secretary (Drugs Regulation), Ministry of Health and Family Welfare, Government of India, U-6, Work Hall, C Wing, First Floor, Kartavya Bhawan-1, New Delhi–110001, or via email at **drugsdiv-mohfw [at]gov[dot]in.**

The Official Gazette can be accessed through this link: **https://egazette.gov.in/(S(vgjbg1v51kl1b3qx5voh12qg))/ViewPDF.aspx**

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