Union Health Ministry has proposed amendments to Drugs Rules, 1945 to mandate Authorisation of qualified personnel for drug batch release

Amendments to the Drugs Rules, 1945 seek to strengthen accountability and documentation in batch release

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Union Ministry of Health and Family Welfare has proposed amendments to the Drugs Rules, 1945, to mandate drug manufacturers to formally authorise a person with appropriate qualifications and experience for batch release of drugs and maintain prescribed records for every batch manufactured.

The proposed amendments aim to strengthen accountability in the drug manufacturing process by introducing an explicit regulatory requirement for the authorisation of personnel responsible for batch release. While manufacturing licences currently require manufacturers to furnish details of competent technical staff responsible for manufacturing and testing, there is no specific provision for mentioning the person authorised to undertake batch release.

Under the proposed framework, applicants seeking manufacturing licences under the relevant provisions of the Drugs Rules, 1945, would be required to designate a suitably qualified and experienced person for batch release and maintain batch-release records in accordance with the prescribed requirements. The amendments also propose to introduce a prescribed format for the Batch Release Certificate under the Rules.

Batch release is a critical stage in the pharmaceutical manufacturing process, involving an overall review of the relevant quality parameters and documentation before a batch is released for distribution. The proposed requirements are intended to establish clear responsibility for this function, ensure traceability of batch-release decisions and provide an additional level of oversight of product quality.

The proposed amendments are also expected to support manufacturers in strengthening their compliance with applicable Good Manufacturing Practices (GMP) and reinforce the regulatory framework governing the quality assurance of drugs.

Objections and suggestions, if any, on the proposed amendments may be submitted 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 sent by email to **drugsdiv-mohfw[at]gov[dot]in**.

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