F. No. DC-DT-15011(11)/144/2025-eoffice, e-file 28466
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Dated:
07 OCT 2025

To,

All State/ UT Drug Controllers

Subject: Strict compliance with the Drugs Rules, 1945, for testing of raw materials and finished formulations - regarding

Sir/ Madam,

This Directorate has time to time emphasized the critical importance of testing of raw materials including the excipients before its use in the manufacturing of pharmaceutical formulations.

There have been recent reports of child deaths in Chhindwara, Madhya Pradesh, allegedly linked to contaminated cough syrups and concerns related to quality of these cough syrups.

Further during the inspections carried out at the manufacturing facilities and in the investigations of the drugs declared as Not of Standard Quality, it was observed in the reports that the manufacturers are not carrying out testing of each batch of the excipients/inactive and active pharmaceutical ingredients for verification of compliance with the prescribed standards before using them in the manufacture of formulations and also in the finished products.

It is to mention that as per Drugs Rules including rule 74 (c) and rule 78 (c) (ii), the licensee shall either in his own laboratory or in any laboratory approved by the licensing authority test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U.

All the State/ UT Drug Controllers are requested to take measures to ensure testing before the manufacture and release of the batch to the market by way of monitoring during inspections, sensitising the manufacturers through circulars, etc. Further, it shall also be ensured that the manufacturers have robust vendor qualification system in place and use raw materials including excipients from reliable approved vendors only.

You are requested to acknowledge the receipt of this letter and intimate the action taken in this regard.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to: 1. PPS to DGHS, MoHFW, Nirman Bhawan, New Delhi
2. PS to Joint Secretary (Regulation), MoHFW, Nirman Bhawan, New Delhi
3. Website of CDSCO