GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. †995
TO BE ANSWERED ON 05TH DECEMBER, 2025

IMPLEMENTATION OF GOOD MANUFACTURING PRACTICES (GMP)

†995. SHRI KAUSHALENDRA KUMAR:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Government is considering relaxing the time limit applicable for pharmaceutical companies to implement Good Manufacturing Practices (GMP);

(b) if so, the details thereof;

(c) whether several pharmaceutical companies have not been able to implement GMPs yet; and

(d) if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (d): Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover > Rs. 250 crores from 29.06.2024. However, for manufacturers having turnover of less than Rs. 250 Cr, conditional extension has been granted up to 31.12.2025 for those who submitted their upgradation plan.

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