

F. No. 12-107/2023-DC(Pt-MISC-SND)
Central Drugs Standard Control Organisation
Ministry of Health and Family Welfare
Govt. of India
(SND DIVISION)

Date: 5th December, 2023

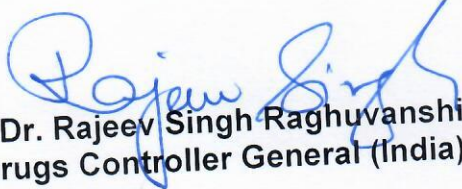
ADVISORY

Under the Drugs and Cosmetics Act and Rules there under the drug manufacturers are required to manufacture the drugs adhering strictly to the conditions of manufacturing license and prescribed Good Manufacturing Practices to ensure that the drugs manufactured for marketing are of quality standards and meets the parameters of quality, safety and efficacy.

In order to ensure quality, safety and efficacy of drugs formulation it is of paramount importance that such formulation are manufactured in compliance with the prescribed standards not only in respect of API but also various excipients used for manufacturing of the formulations. Therefore, the quality, safety and efficacy of both APIs and the excipients are crucial.

In case of manufacture of cough syrups, various critical excipients like propylene glycol, glycerine, sorbitol etc. are used. The manufacturers are required to ensure that these excipients meet the regulatory standards of quality so as to avoid any contamination in the formulations manufactured by using such excipients During winter seasons, there may be increase in use of cough syrups in the country.

In view of above, the manufacturers are hereby advised that they should purchase and use only pharma grade excipients from their approved sources/vendors which are of quality standards in accordance with the regulatory requirements under the provisions of the said Act & Rules to ensure quality, safety and efficacy of the drug formulations.


Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)

To
All Stakeholders & CDSCO Website

Copy to:

- 1) All State / UT Drugs Controllers to direct all the manufacturers under their jurisdiction to use only pharma grade excipients in manufacturing of drug formulations
- 2) All Zonal & Sub Zonal offices of CDSCO for follow up with the concerned State

Copy for information to:

- 1) PPS to AS (Regulation), MoHF&W, Nirman Bhawan, New Delhi