

Adv. No.09/DCA-Peshi/2023.**Dated : 11/08/2023****ADVISORY****Sub:** Procurement and testing of the raw materials Glycerin & Propylene Glycol by the Cough Syrup manufacturers – Reg.*** * ***

All the Cough syrup manufacturers in Telangana State are requested to adhere to the following aspects regarding procurement and testing of the raw materials "Glycerin" & "Propylene Glycol" before consuming the same for production of formulations:

a) If Glycerin & Propylene Glycol are used as 'Pharmaceutical Aid/ Excipient', they shall be procured directly from the manufacturers, as required as per Para 10.3 of Part I of Schedule-M of Drugs Rules. The raw materials 'Glycerin' & 'Propylene Glycol' shall comply with the pharmacopoeial standards.

b) Glycerin & Propylene Glycol must be tested for 'Diethylene Glycol & Ethylene Glycol' (with a Limit: Not More Than 0.10%) as per the pharmacopoeial monographs of Glycerin & Propylene Glycol before consuming the same for production of formulations.

c) As an abundant precaution, you are requested to sample and test/analyse **all** the individual containers/packs of Glycerin & Propylene Glycol on receipt of raw material.

Kamalan Reddy
DIRECTOR GENERAL *11/8/23*

To
All the Cough Syrup manufacturers in the state.

Copy to :

All the Drugs Inspectors in the State are instructed to communicate to the concerned manufacturers in their jurisdiction.
All the Assistant Directors in the State.
All the Deputy Directors in the State

Copy submitted to :

The Drugs Controller General (India), CDSCO, New Delhi for information.