No. F.6-30/2022-QA
Government of Pakistan
Drugs Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination
TF Complex, Sector G-9/4, Islamabad
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Islamabad, the 21st October, 2022

The Additional Director, Drug Regulatory Authority of Pakistan, **Lahore.**	The Additional Director, Drug Regulatory Authority of Pakistan, **Karachi.**
The Officer Incharge, Drug Regulatory Authority of Pakistan, **Quetta.**	The Additional Director, Drug Regulatory Authority of Pakistan, **Peshawar.**
The Additional Director, Drug Regulatory Authority of Pakistan, **Islamabad.**	The Chief Drug Controller, Government of Punjab, **Lahore.**
The Chief Drug Inspector, Government of Sindh,**Karachi.**	The Chief Drug Inspector, Government of Khyber Pakhtunkhwa, **Peshawar.**
The Senior Drug Inspector, ICT, **Islamabad.**	The Chief Drug Inspector, Government of Balochistan, **Quetta.**
The Chief Drug Controller, Government of Gilgit Baltistan, **Gilgit.**	The Chief Drug Inspector, Government of AJK, **Muzafarabad.**

"DRUG IMPURITY ALERT"

Subject: - **Testing of Solvents Glycerin, Propylene Glycol & Sorbitol used in Oral Preparations for Presence of Any Toxic Impurities Namely Diethylene Glycol (DEG) & Ethylene Glycol (EG).**

I am directed to refer the subject noted above and to say that Glycerin, Sorbitol & Propylene glycol are widely used in therapeutic goods as solvent. Adulteration of these materials with highly toxic Diethylene Glycol (DEG) and Ethylene Glycol(EG) had been reported in many countries in past. DEG and EG are poisonous and may lead to severe health injury or death. Incidents of severe health injury/deaths of children as recently reported in Gambia due to consumption of cough syrup containing glycerin urges for an emergent need of vigilant monitoring of these possible contaminants.

2. In this situation it becomes essential to perform test/analysis of these solvents for presence of any toxic impurity/contaminants specially when used in oral dosage forms such as syrups/suspensions etc. It is legal responsibility of all manufacturers of therapeutic goods to ensure before marketing that all the manufactured therapeutic goods are safe for consumption. Therefore, it is required that all manufacturers using these solvents must perform proper testing

to detect DEG and EG contamination. Following measures/practices must be implemented while manufacturing of glycerin, sorbitol and propylene glycol containing oral dosage forms:

a) All the manufacturers of therapeutic goods are strictly bound to use pharmaceutical grade solvents purchased from qualified vendors only.

b) Therapeutic goods manufacturers should perform specific identity that include limit test for DEG and EG on all containers of all lots of these solvents before use. The relevant safety limit of DEG and EG is 0.1% as recognized by the USP monograph for these solvents.

c) No manufacturer shall be allowed to consume these solvents in oral preparations unless otherwise it provides certificate of analysis clearly showing the performance of specific identity that include limit test for DEG and EG.

d) The manufacturers shall submit a test/analysis report for already manufactured batches of these products within three (3) days positively and if any out of specification is reported the product shall be recalled at once otherwise strict regulatory action will be initiated against the manufacturer.

e) The Federal and Provincial Drug Inspectors may be advised to carry out the risk based sampling of oral dosage forms/preparations especially the cough syrups containing these solvents for test/analysis by the Laboratories.

f) Reports of activities by the FIDs/PDIs regarding the actions taken may be shared to this division on weekly basis.

(Fahad Nadeem)
Deputy Director (LT)
QA & LT Division DRAP
Islamabad

Copy to:-

1. The Director H&OTC with request to intimate all the enlistment holders.
2. The Pakistan Pharmaceutical Manufacturing Association.
3. The Pharma Bureau Pakistan.
4. File No.F.6-30/2022-QA
5. Master Folder.

Deputy Director (LT)
QA & LT Division DRAP
Islamabad