Pharmacopoeial and Regulatory Resources for Identifying Ethylene Glycol and Diethylene Glycol in Medicines

The Indian Pharmacopoeia Commission (IPC) plays a pivotal role in safeguarding public health by establishing pharmacopeial standards and providing reference substances that ensure the safety, efficacy, and quality of medicines. The IPC has developed a free toolkit by compiling pharmacopoeial and regulatory resources to address contamination with high levels of diethylene glycol (DEG) and ethylene glycol (EG) associated with liquid oral medicines, particularly in allergy, cold, and cough syrups. This document serves as a comprehensive reference, compiling key general chapters and monographs from the Indian Pharmacopoeia (IP), available reference standards, along with relevant international guidance's. The resources are intended to support excipients and raw material suppliers, drug manufacturers, testing laboratories, and regulatory agencies.

General Chapters and General Monographs of the IP

General Chapters and General Monographs in the IP provide foundational principles, standardized test methods, and quality assurance procedures that are applicable across multiple monographs. These chapters serve as essential references for ensuring consistency in analytical testing and manufacturing practices.

In the context of DEG and EG contamination, relevant general chapters offer validated methods and quality control frameworks that help manufacturers detect impurities, assess excipient integrity, and maintain compliance with pharmacopeial standards. By implementing these chapters effectively, stakeholders can strengthen control over high-risk excipients and safeguard the quality and safety of liquid oral formulations.

- General Chapter {2.4.13} Gas Chromatography - Analytical procedure for performing gas chromatography
- General Monograph Oral Liquids - Mandatory quality tests to be performed on finished formulations

Excipient Monographs of the IP

Following IP monographs provide quality specifications for key excipients:

- Glycerin
- Liquid Maltitol
- Polyethylene Glycol 1500
- Polyethylene Glycol 4000
- Polyethylene Glycol 6000
- Propylene Glycol
- Sorbitol Solution (70 per cent) (Crystallising)
- Sorbitol Solution (70 per cent) (Non-Crystallising)

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IPC Updates

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IP Reference Standards (IPRS)

To ensure analytical accuracy and traceability, the relevant IP Reference Standards (IPRS) materials are available through the IPC as mentioned below.

- Diethylene Glycol IPRS
- Ethylene Glycol IPRS
- Glycerin (Glycerol) IPRS
- Propylene Glycol IPRS
- Sorbitol IPRS
- Maltitol (Mannitol Impurity B) IPRS

Users can access and purchase IPRS by visiting at https://onlinestore.ipc.gov.in. For any queries related to purchasing IPRS, please write to sales-ipc@gov.in.

IPC Guidance on Testing of DEG and EG by Gas Chromatography

- IPC/GD/11: Testing of Diethylene Glycol and Ethylene Glycol in Liquid Orals by Gas Chromatography

Legislations and Advisories by the Government of India

- CDSCO advisory on Strict compliance with the Drugs Rules, 1945, for testing of raw materials and finished formulations
- G.S.R.922 (E) Notification on Revised Schedule M
- DGHS advisory on rational use of cough syrups in Paediatric Population
- CDSCO advisory on use of pharma grade excipients in manufacturing of drug formulations
- List of approved NABL Accredited Private Testing Laboratories for testing of Cough Syrups to be exported by the Manufacturer/ Authorize person of Manufacturer/ Exporter

Supporting Global Resources

- WHO TRS 1052 Annex 2: Good Manufacturing Practices for Excipients
- International Pharmacopoeia test method for DEG and EG in Oral Liquid Preparations