



## MEDICAL PRODUCT ALERT

DRAP ALERT NO. N° I/S/01-24-05

### RECALL OF SYRUPS DUE TO CONTAMINATION OF ETHYLENE GLYCOL

**Date:** 30<sup>th</sup> January, 2024.

#### Target Audience:

- National Regulatory Field Force.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

#### Alert Summary:

Government Analyst DTL Bahawalpur and DTL Rawalpindi have informed that following products are found to be of “sub-standard” quality due to presence of Ethylene Glycol (EG) impurity at unacceptable levels. Details of test reports are as under:

S#	Product Name	Batch No.	Manufactured by	Test Results
01	<b>Asthanil 60ml Syrup</b> (Ketotifen 1mg/5ml)	03-23	M/s. Siza International (Pvt.) Ltd., 18-Km Ferozpur Road, Lahore.	Ethylene Glycol: 2.896% <b><u>Does not comply</u></b>
02	<b>Virol Syrup</b> (Ribavirin 5mg/5ml)	35080	M/s. Raazee Therapeutics (Pvt.) Ltd., 48-Km Lahore- Kasur Road, Lahore.	Ethylene Glycol: 3.31% <b><u>Does not comply</u></b>
03	<b>Torax DM Syrup</b> Each 5ml contains: Dextromethorphan HBr 12.5mg & Diphenhydramine HCl 12.5mg	110-23	M/s. Siza International (Pvt.) Ltd., 18-Km Ferozpur Road, Lahore.	Ethylene Glycol: 2.14% <b><u>Does not comply</u></b>
04	<b>Texcol EX Syrup</b> Each 5ml contains: Acefylline Piperazine 45mg, Diphenhydramine HCl 8mg	63833	M/s. Raazee Therapeutics (Pvt.) Ltd., 48-Km Lahore- Kasur Road, Lahore.	Ethylene Glycol: 0.985% <b><u>Does not comply</u></b>
05	<b>Texcol DM Syrup</b> (Dextromethorphan HBr 10mg/5ml)	09953	M/s. Raazee Therapeutics (Pvt.) Ltd., 48-Km Lahore- Kasur Road, Lahore.	Ethylene Glycol: 1.19% <b><u>Does not comply</u></b>



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06	<b>Allerphene Syrup</b> Chloepheneramine Maleate 2mg/5ml)	3002	M/s. PDH Pharmaceuticals (Pvt.) Ltd., 19-Km Ferozpur Road, Lahore.	Ethylene Glycol: 1.417% <b><u>Does not comply</u></b>
07	<b>Speczine Syrup</b> (Promethazine HCl 5mg/5ml)	276	M/s. Spectrum Laboratories (Pvt.) Ltd., 8-Km Raiwind Road, Lahore.	Ethylene Glycol: 2.43% <b><u>Does not comply</u></b>
08	<b>Bronyl syrup</b> (Nutraceutical cough preparation)	BL-013	M/s. Florex Pharma Pvt Ltd, 25-Km Lahore-Jaranwala Road, Sheikhpura-Lahore.	Ethylene Glycol: 0.12% <b><u>Does not comply</u></b>

#### Action initiated: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

#### Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by affected batches of mentioned products. Adverse reactions or quality problems experienced with the use of these products are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this [link](#). Further information of reporting problems to DRAP is available on this [link](#).

#### Advice for Consumers / general public: -

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.



## Drug Regulatory Authority of Pakistan

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