

MEDICAL PRODUCT ALERT

RECALL OF SYRUPS DUE TO CONTAMINATION OF ETHYLENE GLYCOL

Date: 30th January, 2024.

Target Audience:

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

Alert Summary:

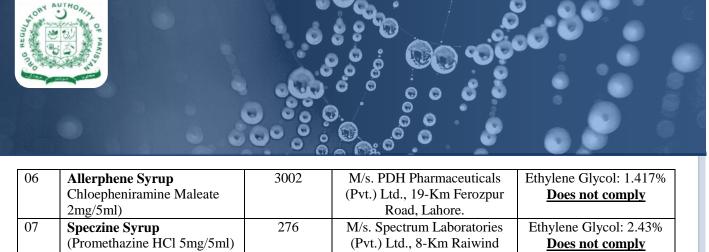
Government Analyst DTL Bahawalpur and DTL Rawalpindi have informed that following products are found to be of "sub-standard" quality due to presence of Ethylene Glycol (EG) impurity at unacceptable levels. Details of test reports are as under:

S#	Product Name	Batch No.	Manufactured by	Test Results
01	Asthanil 60ml Syp (Ketotifen 1mg/5ml)	03-23	M/s. Siza International (Pvt.) Ltd., 18-Km Ferozpur Road, Lahore.	Ethylene Glycol: 2.896% Does not comply
02	Virol Syrup (Ribavirin 5mg/5ml)	35080	M/s. Raazee Therapeutics (Pvt.) Ltd., 48-Km Lahore- Kasur Road, Lahore.	Ethylene Glycol: 3.31% Does not comply
03	Torax DM Syrup 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% Does not comply
04	Texcol EX Syrup 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% Does not comply
05	Texcol DM Syrup (Dextromethorphan HBr 10mg/5ml)	09953	M/s. Raazee Therapeutics (Pvt.) Ltd., 48-Km Lahore- Kasur Road, Lahore.	Ethylene Glycol: 1.19% Does not comply

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	(Promethazine HCl 5mg/5ml)		(Pvt.) Ltd., 8-Km Raiwind	Does not comply
			Road, Lahore.	
08	Bronyl syrup	BL-013	M/s. Florex Pharma Pvt Ltd,	Ethylene Glycol: 0.12%
	(Nutraceutical cough		25-Km Lahore-Jaranwala	Does not comply
	preparation)		Road, Sheikhupura-Lahore.	
			-	

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 محفوظ، مونثر اور معیاری اشیائے علاج

