

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা
www.dgda.gov.bd

তারিখঃ...../...../২০২৪ খ্রীঃ

নং- ডিজিডিএ/ এলাট-নোটিশ/এমসি-১৬/২০১৯

অফিস আদেশ

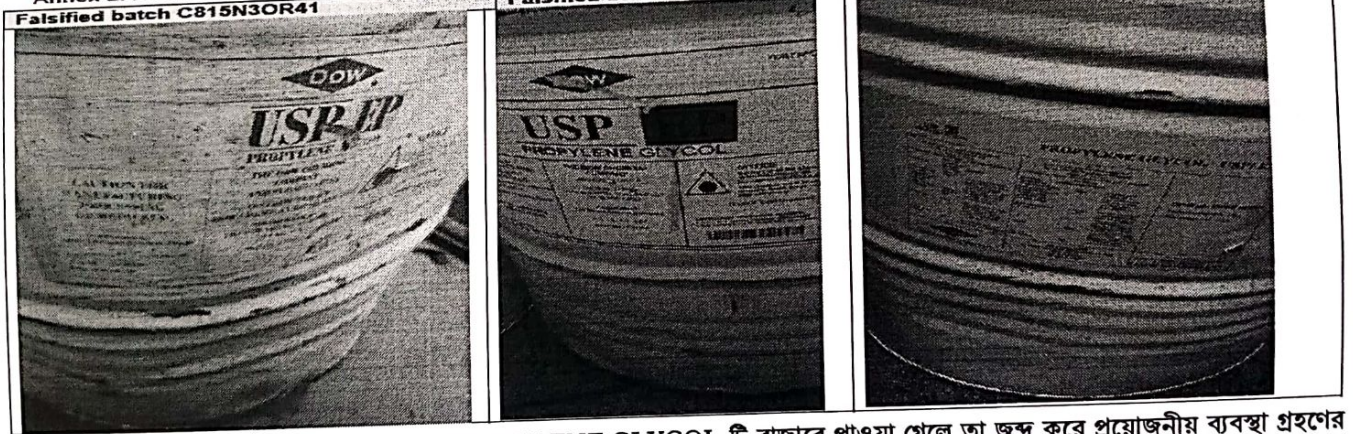
ঔষধ প্রশাসন অধিদপ্তরের মাঠ পর্যায়ের সকল কর্মকর্তাদের জানানো যাচ্ছে যে, বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলাট 1/2024 এ এই মর্মে সতর্ক করেছে যে, পাকিস্তানের বাজারে মান বহির্ভূত (ডেজাল) হিসেবে DOW USP/EP PROPYLENE GLYCOL পাওয়া যাচ্ছে। এক্সিপিফেন্ট হিসেবে ব্যবহৃত উক্ত DOW USP/EP PROPYLENE GLYCOL পাকিস্তানের সেন্ট্রাল ড্রাগস ল্যাবরেটরীতে পরীক্ষা করা হলে দেখা যায় যে, এতে Ethylene Glycol অগ্রহণযোগ্য মাত্রায় কন্টামিনেন্ট বা ডেজাল হিসেবে আছে। Ethylene Glycol মানব শরীরের জন্য ক্ষতিকর ও অনেক ক্ষেত্রে প্রাণঘাতী।

Annex 1: Products subject of WHO Medical Product Alert No. 1/2024
DOW USP EP PROPYLENE GLYCOL

Product Name Stated	Manufacturer	Batch Number	Mfg. Date	Expiry Date	Authenticity of Batch	Identified In
Dow Chemical, Thailand Ltd	Dow Chemical, Thailand Ltd	C815N3OR41	03-23	03-25	Genuine batch number	Pakistan
Dow Chemical Pacific (Singapore) Private Limited	Dow Chemical Pacific (Singapore) Private Limited	C815L44R41	Not reported	Not reported	Genuine batch number (expiry date April 2023)	Pakistan
Dow Chemical, Thailand Ltd	Dow Chemical, Thailand Ltd	C815L44R52	Not reported	Not reported	Falsified batch number	Pakistan
		C856H85R55	2023 01 15	2025 01 15	Falsified batch number	Pakistan

Product Name Stated	Manufacturer	Batch Number	Mfg. Date	Expiry Date	Authenticity of Batch	Identified In
PROPYLENE GLYCOL USP/EP	Dow Europe, GmbH, Germany	F8900L8PPD6	Feb 2023	Feb 2025	Falsified batch number	Pakistan

Annex 2: Available photographs - WHO Medical Product Alert No. 1/2024



এমতাবস্থায় উল্লেখিত ব্যাচ এর DOW USP/EP PROPYLENE GLYCOL টি বাজারে পাওয়া গেলে তা জব্দ করে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য এতদ্বারা নির্দেশ প্রদান করা গেল।

১. সংযুক্তিঃ ০৩ (তিন) পাতা


20/08/24
মোঃ আসরাফ হোসেন
পরিচালক

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হেড অব মার্কেট সার্ভিল্যান্স এন্ড কন্ট্রোল
ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।
ফোনঃ ০২২২২২-৮০৮০৩
মোবাইলঃ ০১৮১৯-১৪০৪২১
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Medical Product Alert No. 1/2024
Falsified (contaminated) USP/EP PROPYLENE GLYCOL identified in the
WHO Eastern Mediterranean Region

Alert Summary

This WHO Alert refers to falsified DOW USP/EP PROPYLENE GLYCOL detected in Pakistan. Authentic DOW USP/EP PROPYLENE GLYCOL is a raw material (excipient) utilized in pharmaceutical and other manufacturing processes, adhering to the standards of the United States and European Pharmacopoeias (USP/EP) for medicinal use.

Background

WHO has previously published seven Alerts on contaminated oral liquid medicines. Please see [Medical Product Alert No.6/2022](#), [Medical Product Alert No.7/2022](#), [Medical Product Alert No.1/2023](#), [Medical Product Alert No.4/2023](#), [Medical Product Alert No.5/2023](#), [Medical Product Alert No.6/2023](#) and [WHO Medical Product Alert N°8/2023](#).

Following WHO Medical Product Alert N°8/2023 in December 2023, the Drug Regulatory Authority of Pakistan (DRAP) investigated potential contamination of oral liquid medicines. Suspect drums of PROPYLENE GLYCOL were identified by DRAP, and samples were tested by Pakistan's Central Drugs Laboratory. The analyses revealed unacceptable levels of ethylene glycol contamination, ranging from 0.76% to 100%. Between January and March 2024, DRAP issued three Rapid Alerts regarding five contaminated batches of DOW USP/EP PROPYLENE GLYCOL.

- [DRAP Alert No I/S/01-24-02 \(11 Jan 2024\)](#)
- [DRAP Alert No I/S/02-24-11 \(7 March 24\)](#)
- [DRAP Alert No I/S/03-24-14 \(11 March 2024\)](#)

DOW has confirmed that the raw materials detailed in the DRAP Alerts and identified in this WHO Alert are falsified and were not manufactured or supplied by DOW. The quality and safety of these excipients therefore cannot be assured.

The PROPYLENE GLYCOL materials identified in this Alert are considered to have been deliberately and fraudulently mislabelled. They contain high levels of ethylene glycol, which if ingested can be toxic. These raw materials may have been distributed to other countries, including through informal or unregulated markets. Manufacturers of oral liquid medicines may have unknowingly purchased these contaminated raw materials, which may still be in their storage facilities.

Please refer to [Annex 1](#) of this Alert for full details of the affected products and [Annex 2](#) for available photographs.

Risks

Ethylene glycol is toxic to humans when consumed and can prove fatal.

The falsified raw materials referenced in this Alert should be considered as unsafe and their use in medical products may result in serious injury or death, particularly in children. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
Please visit: <https://www.who.int/health-topics/substandard-and-falsified-medical-products>, or e-mail: rapidalert@who.int

Advice to manufacturers, distributors, and regulatory authorities

Manufacturers of medicines should ensure that raw materials are acquired from qualified and approved suppliers.

Manufacturers of oral liquid medicines, especially syrups containing raw materials at risk of contamination with ethylene glycol (EG) and/or diethylene glycol (DEG), e.g. propylene glycol, sorbitol, and/or glycerin/glycerol, are urged to follow WHO good manufacturing practice requirements.

Manufacturers are also advised to test each batch of incoming raw materials for ethylene glycol and diethylene glycol before using as excipients in the production of liquid medicines.

Analytical methods have been developed for testing paediatric medicines contaminated with DEG/EG. Gas Chromatography (GC) is a suitable and widely used analytical technique. In case of lack of access to GC, in the International Pharmacopoeia WHO recommends a two-level approach in which suspicious samples are first screened to quickly identify contamination using a semi-quantitative thin-layer chromatography (TLC) method. The suspected contaminated products may then be confirmed by GC.

WHO advises against distributing or promoting any finished products that may have been manufactured using the potentially affected raw materials, without undergoing further testing. If such products have already been distributed and consumed, it is crucial to urge and guide patients to promptly seek medical advice from a healthcare professional.

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these affected raw materials. Increased surveillance of the informal/unregulated market is also advised. National regulatory authorities/health authorities are advised to immediately notify WHO if substandard/falsified raw materials are discovered in their respective country.

Healthcare professionals should report any cases of adverse events suspected to be linked to the use of contaminated medicines to the National Regulatory Authorities/National Pharmacovigilance Centre. Patients who experience adverse reactions or unexpected side effects after using suspected contaminated products should also seek immediate medical attention from a healthcare professional.

If you have any information about the manufacture, use or supply of these falsified and contaminated raw materials, please contact WHO via rapidalert@who.int.

Annex 1: Products subject of WHO Medical Product Alert No. 1/2024

Product Name	DOW USP EP PROPYLENE GLYCOL			
Stated Manufacturer	Dow Chemical, Thailand Ltd	Dow Chemical Pacific (Singapore) Private Limited		Dow Chemical, Thailand Ltd
Batch Number	C815N3OR41	C815L44R41	C815L44R52	C856H85R55
Mfg. Date	03-23	Not reported	Not reported	2023 01 15
Expiry Date	03-25	Not reported	Not reported	2025 01 15
Authenticity of Batch	Genuine batch number	Genuine batch number (expiry date April 2023)	Falsified batch number	Falsified batch number
Identified in	Pakistan			

Product Name	PROPYLENE GLYCOL USP/EP
Stated Manufacturer	Dow Europe, GmbH, Germany
Batch Number	F8900L8PPD6
Mfg. Date	Feb 2023
Expiry Date	Feb 2025
Authenticity of Batch	Falsified batch number
Identified in	Pakistan

Annex 2: Available photographs - WHO Medical Product Alert No. 1/2024


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