METHODS FOR THE DETECTION OF ETHYLENE GLYCOL AND DIETHYLENE GLYCOL IN MEDICINAL PREPARATIONS: RELEVANCE, CLASSICAL AND PROMISING SCREENING APPROACHES

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This review summarizes and analyses methods for controlling ethylene glycol (EG) and diethylene glycol (DEG) impurities in pharmaceutical products. Contamination of medicinal products with these substances threatens the safety of patients, which is confirmed by numerous mass poisoning incidents throughout history and in modern times. The main reason is using toxic glycols instead of safe fillers such as propylene glycol and glycerol. The article presents systematic review of modern EG and DEG determining methods that range from standard pharmacopoeia methods to perspective screening tools. Particular attention is given to the relevance of development and implementation of prompt, precise and affordable screening solutions to be used at all stages of the pharmaceutical supply chain. The World Health Organization (WHO) Initiatives, including the target product profile (TPP), which aims to enforce these solutions, have been reviewed. It is emphasized that shifting from traditional centralized laboratory testing to decentralized methods is essential to prevent falsification and ensure safety of patients.

Keywords: ethylene glycol, diethylene glycol, pharmacopoeia analysis, chromatography, drug adulteration, pharmaceutical safety, screening methods, World Health Organization (WHO)

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МЕТОДЫ ОБНАРУЖЕНИЯ ЭТИЛЕНГЛИКОЛЯ И ДИЭТИЛЕНГЛИКОЛЯ В ЛЕКАРСТВЕННЫХ ПРЕПАРАТАХ: АКТУАЛЬНОСТЬ, КЛАССИЧЕСКИЕ И ПЕРСПЕКТИВНЫЕ СКРИНИНГОВЫЕ ПОДХОДЫ

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В данном обзоре систематизированы и проанализированы методы контроля токсичных примесей этиленгликоля (ЭГ) и диэтиленгликоля (ДЭГ) в фармацевтической продукции. Проблема загрязнения лекарственных средств данными веществами представляет собой глобальную угрозу безопасности пациентов, что подтверждается многочисленными историческими и современными случаями массовых отравлений. Основной причиной является использование токсичных гликолей вместо безопасных наполнителей, таких как пропиленгликоль или глицерин. В статье представлен систематический обзор современных методов определения ДЭГ и ЭГ — от стандартных фармакопейных до перспективных скрининговых технологий. Особое внимание уделено актуальности разработки и внедрения быстрых, точных и экономически доступных скрининговых решений для применения на всех этапах фармацевтической цепочки поставок. Рассмотрены инициативы Всемирной организации здравоохранения, в том числе проект целевых профилей продукции (ЦПП), направленные на стимулирование создания таких решений. Подчеркнута важность перехода от централизованной лабораторной диагностики к децентрализованным технологиям для предотвращения фальсификаций и обеспечения безопасности пациентов.

Ключевые слова: этиленгликоль, диэтиленгликоль, фармакопейный анализ, хроматография, фальсификация лекарственных средств, фармацевтическая безопасность, скрининговые методы, Всемирная организация здравоохранения (ВОЗ)

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The purity of pharmaceuticals and finished products is crucial for modern medicine. Even trace amounts of highly toxic impurities in medications can be dangerous because they can reduce therapeutic effectiveness and cause serious health problems. Ethylene glycol (EG) and diethylene glycol (DEG) impurities are toxic contaminants that enter medicinal preparations and liquid oral medicines, like syrups and suspensions in particular, through poor quality and falsified excipients such as glycerol, propylene glycol, polyethylene glycol and sorbitol [1, 2]. (A more detailed description of risks for every substance is provided in Exhibit).

The toxicological danger of EG and DEG stems from different metabolic pathways. EG and DEG are converted by the alcohol dehydrogenase to glycolic and glyoxylic acids

(for EG) and 2-hydroxyethoxy acetic acid (for DEG). These metabolites cause severe metabolic acidosis, crystalluria, and direct nephrotoxic effects, leading to acute tubular necrotization and, as a result, acute renal failure with a high mortality rate, especially among children [3, 4].

Not only theoretical assumptions but also empirical evidence with disastrous medical and social effects confirm that the problem is relevant.

There are numerous cases in history when drugs were responsible for the deaths of many people:

- USA, 1937: 107 people died after taking Elixir Sulfanilamide. The deaths were caused by DEG used as a solvent for the drug. The tragedy spurred the Federal Food, Drug, and Cosmetic Act, which tightened the requirements for preclinical safety studies [5];
- Haiti, 1995–1996: paracetamol syrup based on DEG-contaminated glycerin was the cause of a large outbreak of acute renal failure deaths among over 80 children [6];
- Panama, 2006: massive poisoning with cough syrups, which lead to numerous deaths. Cheap technical-grade glycerin contaminated with DEG was used to manufacture the medicines [7].

The largest recent outbreak occurred in 2022–2023 when more than 300 children in Gambia, Indonesia, Uzbekistan and other countries died of acute kidney injury, associated with contaminated cough syrups and antipyretics [8–10]. India has also declared cough syrups containing DEG and EG as toxic following the deaths of children in October 2025. The World Health Organization (WHO), which issued a series of global health alerts, and regulatory authorities around the world responded immediately [11, 12]. Thus, the issue, which is not local but global, requires a systemic response, including stricter regulatory controls and development of new analytical solutions.

The goal of this review is to systematize data about classical and modern methods for determination of EG and DEG and justify the critical need to introduce into practice the screening methods that can prevent similar catastrophes in the future.

1. CLASSICAL AND REFERENCE METHODS OF ANALYSIS

The global scientific and regulatory community uses chromatographic methods for reliable quantification of EG and DEG in pharmaceuticals due to their selectivity, accuracy, and sensitivity [13].

1.1. Gas chromatography with the flame ionization detector (GC-FID)

The CG-FID method is a primary method regulated in the United States Pharmacopeia (USP), European Pharmacopoeia (Ph. Eur.) and the State Pharmacopoeia of the Russian Federation (SPRF) to test whether glycerol, propylene glycol and other related substances contain EG and DEG [14–16].

During the GC-FID analysis, a sample is subjected to derivatization (for example, silanization) before entering the chromatographic column to improve volatility and chromatographic performance.

The mixture components are separated based on their differing distribution coefficients for a mobile phase (carrier gas) and a stationary phase inside the column. Detection is carried out with a flame ionization detector that uses a hydrogen-fueled flame to ionize organic compounds, ensuring high sensitivity of the method.

Modern GC-FID methods can achieve a limit of quantitative determination (LOQ) of 0.01%, which is ten times lower than the 0.1% permissible threshold for EG and DEG set by regulatory bodies. The methods provide excellent reproducibility and linearity over a wide concentration range, making them suitable for quantitative analysis in various matrices [17]. The advantages of the method include high selectivity, reliability, accuracy of quantitative analysis, and wide acceptance by regulatory authorities. The GC-FID method, however, has certain limitations such as high cost of equipment, need in skilled personnel, and a lengthy sample preparation process, including the stage of derivatization. Moreover, the stationary equipment used hinders on-site, field, or remote analyses.

1.2. Gas Chromatography-Mass Spectrometry (GC-MS)

Gas Chromatography-Mass Spectrometry (GC-MS) is justifiably considered the “gold standard” for confirming the authenticity of toxic impurities and solving complex analytical problems.

After being separated by the chromatographic column, the individual components of a sample enter the mass spectrometer, where they are first ionized, then fragmented, and finally detected by their mass-to-charge ratio. A mass spectrum from the GC-MS analysis serves as a unique “fingerprint” for a molecule, allowing for high-accuracy identification, even in complex mixtures.

The method is widely used to unambiguously confirm the presence of ethylene glycol and diethylene glycol in samples when there are doubts about the GC-FID results, as well as to analyze complex matrices, where the peaks of impurities may overlap with the peaks of other components [18].

The main advantages of the method include exceptional selectivity and sensitivity, as well as the ability to run both non-target analysis in full scan mode and target ion monitoring for increased sensitivity to target compounds.

The method, however, has significant limitations. Thus, the equipment characterized by high purchase and operation costs requires highly qualified operators.

2. THE NEED FOR SCREENING SOLUTIONS AND WHO INITIATIVE

Though classical and reference laboratory methods have a high analytical accuracy, they are not without the limitations such as high cost and limited sensitivity. GC-MS equipment can cost hundreds of thousands of US dollars, and single analyses often take several hours. The economic and logistical demands of managing every raw material and finished product batch are often impractical, especially for businesses in low- and middle-income countries. Meanwhile, the use of poor-grade or adulterated raw materials in these regions is a high-risk concern. It was clearly demonstrated through the tragic incidents in 2022–2023.

The WHO that had recognized the problem developed a Target Product Profile (TPP) for screening devices to detect DEG and EG contamination in medicines and excipients [19]. The regulatory document, which is currently seeking public comments, provides information about the minimum and preferred technical specifications for two categories of analytical devices for different levels of the supply chain.

The first category of TPPs is intended for high-level administrative bodies like national regulatory authorities, sanitary, and customs services. These systems have high analytical accuracy, ability to quantify trace impurities and integrate with software for registration and reporting.

The second category focuses on the product's direct application at the lower level of the chain, such as on production sites, in pharmacies, or within medical organizations. The devices have to be portable, easy to operate (including detected/not detected issues), have low cost of analysis, autonomous power without a connection, and no consumables.

The WHO Target Product Profiles (TPPs) include the following indicators for the key requirements to a medical product. Detection limit: the qualitative method must detect an analyte at concentrations as low as 0.1% (weight), while the quantitative method must be able to reliably quantify it at concentrations as low as 0.03% (weight).

Analytical performance: to pass, the qualitative test with a threshold of 0.1% should have at least 95% of sensitivity and at least 85% specificity.

The time characteristics for the analysis are less than 2 hours to obtain a result, while the optimal interval is under 10 minutes.

Portability: The device must be mobile and suitable for use outside the laboratory.

Economic parameters: the equipment cost should be significantly less as compared to gas chromatography-flame ionization detector (GC-FID) systems and have minimal costs per analysis without expensive consumables.

The devices that correspond to the TPPs can provide for the multi-layered control. It consists of fast and cheap screening of all incoming batches of raw materials and selected batches of finished products on site, followed by sending "suspicious" samples to accredited laboratories where they can be confirmed with reference methods.

3. PERSPECTIVE SCREENING METHODS

Active research in the field of screening technologies that correspond to the WHO TPP is being underway.

- Raman spectrometry uses the inelastic scattering of monochromatic light creating a unique spectral "fingerprint" of molecules. Modern portable Raman spectrometers, including surface-enhanced Raman spectroscopy (SERS) devices, can rapidly detect EG and DEG [20]. The advantages of the method include minimal sample preparation, non-destructive analysis, and screening through transparent packaging [21]. The main problems include development of effective substrates for SERS and algorithms for reliable signal isolation of target analytes against the background of a complex matrix of dosage forms.
- NMR spectroscopy — compact low-field NMR spectroscopy in particular — offers an integrated solution for analyzing mixtures by providing fast, minutes-long results with minimal sample preparation. This technique also allows for the simultaneous detection of EG, DEG and a basic compound (glycerol) using unique spectra [22]. The main objectives are to reduce the cost of instruments and simplify the interpretation of spectra for untrained users.
- Portable analytical systems: small-sized gas chromatographs combined with less energy-intensive detectors are being developed. The systems offer sufficient sensitivity and selectivity despite a smaller size and low cost.
- Thin-layer chromatography (TLC) is a simple and cost-effective technique for detecting ethylene glycol (EG) and diethylene glycol (DEG) impurities in raw materials and liquid dosage forms. It is ideal for situations with limited incoming control resources.

  The procedure involves applying a sample previously diluted with methanol to a silica gel plate, using elution in a solvent system, like a mixture of toluene–acetone–ammonia, and then visualizing them with a detecting agent like iodine vapor (in the presence of starch) or a strong oxidizing agent such as potassium permanganate. The method separates EG/DEG from glycerol, propylene glycol, and matrix carbohydrates. The staining technique has a detection limit of approximately 0.1% (weight percent) and a total analysis time of 20–60 minutes. The main advantages of TLC are low cost, portability and quick development time. It also allows for preliminary screening of samples at a regulatory threshold of ≤ 0.10%. Limitations include semi-quantitative nature of determination, reproducibility and sensitivity being affected by the matrix composition, need in standardizing conditions and using reference compounds because closely related glycols have similar chromatographic mobilities (Rf). All positive or borderline results must undergo confirmation using reference techniques such as gas chromatography with a flame ionization detector (GC-FID) or gas chromatography–mass spectrometry (GC-MS) [23].
- Biosensory and colorimetric methods: They are the most promising for creating cost-effective and easy-to-use test systems (similar to test strips). The principle of action is based on using enzymatic reactions with the formation of a colored product or on the specific binding of antibodies to their targets (immunochromatographic analysis). Achieving high sensitivity and minimizing interference from the sample matrix are crucial when the test systems are developed.
- Fourier transform infrared spectroscopy (FTIR): modern portable FT-IR spectrometers allow for rapid analysis of pharmaceutical products. The method requires specialized algorithms of chemometric analysis to determine EG and DEG impurities [24, 25].
- Microfluidic (labs-on-a-chip) platforms: the systems are of particular interest. Such systems make it possible to automate sample preparation and analysis, minimize reagent consumption, and ensure high reproducibility of results [26].

4. COMPARATIVE ANALYSIS OF ETHYLENE GLYCOL AND DIETHYLENE GLYCOL DETECTION METHODS

Table compares the key analytical and operational parameters of EG and DEG analysis methods. The comparison was based on the principle of action, main advantages and limitations, estimated cost, and portability. The parameters are listed in a decreasing order of sensitivity.

According to the table, a method of analysis is selected based on specific control tasks.

Reference methods (GC-MS, GC-FID) provide the highest sensitivity, but require significant resources. Screening methods (Raman and IR-Fourier spectroscopy, thin-layer chromatography) have reduced sensitivity, but offer advantages

Table. Comparison of some methods of analysis of ethylene glycol (EG) and diethylene glycol (DEG)

Method	Principle of action	Advantages	Limitations	Estimated cost	Portability
GC–MS	Gas Chromatography-Mass Spectrometry	High specificity, gold standard	Expensive to purchase and maintain	Very high	Low
GC-FID	Gas Chromatography-Flame Ionization Detector	High selectivity, quantitative analysis	Requires derivatization, stationary equipment	High	Low
Raman spectroscopy	Inelastic light scattering	A non-destructive and minimal sample preparation technique	The interfering effect of the matrix	Medium (SERS — high)	High
TLC	Elution in a solvent system on a silica gel plate	Simple analysis, low cost, portability	The interfering influence of the matrix, standardization of conditions	Low	High
Fourier transform infrared spectroscopy	Infrared absorption	Rapid analysis, portable devices	Low selectivity	Low	Medium (portable versions are available)

in speed, cost, and the ability to be used in the field. It is optimal to use a multi-level approach, combining timely screening of all batches with selective confirmation of the results by reference methods.

CONCLUSION

Contamination of medicines with ethylene glycol (EG) and diethylene glycol (DEG) is a serious global health challenge. To tackle it, a multi-level approach covering the following key directions is required.

1. Tightening regulatory requirements through mandatory testing of high-risk raw materials and implementation of the quality control recommendations below:
   - mandatory identification testing using specific methods;
   - testing samples from each container of each batch of raw materials;
   - setting a limit of no more than 0.1% for EG and DEG content;
   - mandatory verification of the supply chain and certificates of analysis.
2. Development of modern labs through equipment of accredited labs with modern reference equipment (GC-FID, GC-MS) and preparation of qualified personnel.
3. Introduction of modern screening solutions that correspond to the WHO TPPs to form a multi-leveled quality control system at all stages of the pharmaceutical supply chain.

The use of portable analytical techniques such as Raman spectroscopy is of particular concern as it allows to do as follows:

- rapid analysis without destroying the sample;
- detection through transparent packaging;
- minimal sample preparation;
- high-precision identification of molecules by spectral fingerprints.

Good perspectives of this approach are confirmed by active research in this field, including the one aimed at the development of specialized screening methods for the Russian pharmaceutical market [27].

The tragic mass poisoning should result in international consolidation of efforts of regulatory authorities, manufacturers of diagnostic equipment and the scientific community. Joint collaboration and implementation of modern analytical solutions will allow for development of a reliable pharmaceutical safety system warranting that a patient's life will totally depend on drug effectiveness but not purity.

Exhibit. Detailed analysis of excipients with a high risk of ethylene glycol and diethylene glycol contamination

Excipient	Contamination risk	The main sources of risk	Regulatory documentation
Glycerol	Very high	Byproduct in the biodiesel manufacturing process, incomplete purification	USP Monograph: Glycerin Ph. Eur. 07/2022:0496 ФС.2.2.0006.15 (SPRF)
Propylene glycol	High	Technological impurities from the manufacturing process, falsification	USP Monograph: Propylene Glycol Ph. Eur. 01/2025:0430 ФС.2.1.0169.18 (SPRF)
Polyethylene glycol (macrogol)	Medium-high	Residual monomers, technological impurities	USP Monograph: Polyethylene Glycol Ph. Eur. 01/2005:1123 ФС.2.1.0127 (SPRF)
Sorbitol	High	Incomplete hydrogenation, impurities of raw materials	USP Monograph: Sorbitol Solution Ph. Eur. 01/2005:0436 SPRF: the project is in progress

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