DIETHYLENE GLYCOL & ETHYLENE GLYCOL

BACKGROUND

Diethylene Glycol (DEG) and Ethylene Glycol (EG) are commonly used in antifreeze formulations, have similar physical properties, a slightly sweet taste and **are actually toxic**.

Unfortunately, these substances have been found as **contaminants in some commonly used excipients** which are extensively **used in various oral liquid formulations.** These included **cough syrups, antihistamines, analgesics and antiemetics. Contaminated medications** have recently been **associated with over 300 fatalities,** primarily in young children.

One of the **most common reasons for these incidents** is because manufacturers **relied on the certificate of analysis (COA)** from high-risk product suppliers where the origin of the product was unclear.

RECOMMENDATIONS

The FDA stated, that in order to comply with CGMP regulations, **representative samples of each shipment of each lot of a drug component must undergo appropriate identity testing** before use in drug product manufacturing.

DEG and EG levels **should not exceed 0,10 % in high-risk drug components**, which not only include **glycerin**, but also **propylene glycol (PEG), maltitol solution, hydrogenated starch hydrolysate and sorbitol solution** and many others.

Where applicable, DEG and EG should be tested as **per USP-NF monograph**. If not included in this monograph, the FDA recommends **implementing a suitable and equivalent procedure** that includes a test to reliably detect and quantify DEG and EG.

GMP COMPLIANT DETERMINATION

acc. USP-NF monograph

- Identity testing
- Quantification
- Limit test

GMP COMPLIANT METHOD VALIDATION

incl.

- Method development
- Validation, Revalidation
- Transfer validation

REFERENCE ANALYTICS TECHNOLOGY

- accurate and reliable analysis with GC-MS within very low detection limits

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