

SYNTHETIC PARENTERAL GLYCERIN MEETS USP/EP, GMP

CAS #: 56-81-5

Formula: $C_3H_8O_3$

F.W.: 92.09 g/mol

GLYS-3151

BIO EXCIPIENT GRADE

ANALYSIS	SPECIFICATIONS	
Acidity or Alkalinity (EP)	Passes Test	
Aldehydes (EP)	< = 10 ppm	
Appearance and Color	Clear, Colorless, Viscous Liquid	
Appearance of Solution (EP)	Clear, Colorless Solution	
Assay, Anhydrous Basis (USP/EP)	99.0 – 101.0%	
Chloride (USP/EP)	< = 10 ppm	
Color (USP)	Passes Test	
Fatty Acids and Esters (USP/EP)	Passes Test	
Halogenated Compounds (EP)	< = 35 ppm	
Limit of Chlorinated Compounds (USP)	< = 30 ppm of Cl	
Identification, IR (USP-A/EP-B)	Conforms to Reference Standard	
Identification C (USP)	Conforms to Reference Standard	
Identification A, Refractive Index, 20° C (EP)	1.470 – 1.475	
Purity	> = 99.7%	
Related Substances	Diethylene Glycol (USP-B/EP)	< = 0.1 %
	Ethylene Glycol (USP-B)	< = 0.1%
	Any Individual Unspecified Impurity with RRT < RRT of Glycerin (EP)	< = 0.1%
	Any Individual Unspecified Impurity with RRT > RRT of Glycerin (EP)	< = 0.5%
	Any Individual Unspecified Impurity (USP)	< = 0.1%
	Total Impurities (USP)	< = 1.0%

ANALYSIS	SPECIFICATIONS
Residue on Ignition / Sulfated Ash (USP/EP)	$\leq 0.01\%$
Specific Gravity, 25°C (USP)	≥ 1.249
Specific Gravity, 20°C (EP-C)	1.258 – 1.268
Sugars (EP)	Passes Test
Sulfate (USP)	≤ 20 ppm
Water, KF (USP/EP)	$\leq 2.0\%$

Refer to page 2 for additional product details

General Product Overview

Glycerin, Synthetic, USP, EP is a fully synthetic, Excipient Grade Product, manufactured, packaged, labeled, and tested in FDA registered and inspected cGMP facility in Bangor PA, USA. All operations are conducted in compliance with current Good Manufacturing Practices (cGMP) as defined by 21 CFR Parts 210 and 211 and ICH Q7 Guidance. This product is suitable for use in Insulin manufacturing and other critical pharmaceutical preparations.

Industry Application

Suitable for use as a cGMP parenteral excipient in pharmaceutical manufacturing processes and products.

Key Product Features

- The manufacturing of Synthetic Parenteral Glycerin is performed at BioSpectra's Bangor, PA facility.
- Appears as a clear, colorless, viscous liquid
- Manufactured in accordance with ICH Q7
- Is not subject to genetic modification
- Manufactured in a hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Synonyms: Glycerol; Glycerine; 1,2,3-Propantriol; Propane-1,2,3-Triol; 1,2,3-Trihydroxypropane

Package Sizes

6 x 1L, 4 x 4L, 10L, 200L, 1,000L

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)