

SYNTHETIC PARENTERAL GLYCERIN

MEETS USP/EP/JP/ChP, BET*, GMP

CAS #: 56-81-5

Formula: $C_3H_8O_3$

F.W.: 92.09 g/mol

GLYS-3150

BIO EXCIPIENT GRADE

ANALYSIS	SPECIFICATIONS
Acidity or Alkalinity (ChP/EP/JP)	Passes Test
Aldehydes (EP)	< = 10 ppm
Aldehydes and Related Substances	Passes Test
Glyceraldehyde	< = 5 ppm
Dihydroxyacetone	< = 5 ppm
Hydroxyacetone	< = 5 ppm
Formaldehyde	< = 2 ppm
Acrolein, glucose, or other reducing substances (JP)	Passes Test
Ammonium (ChP/JP)	Passes Test
Appearance and Color	Clear, Colorless, viscous liquid
Appearance of Solution (EP)	Clear, colorless solution
Arsenic (ChP/JP)	< = 0.3 ppm
Assay, Anhydrous Basis (USP/EP/ChP/JP)	99.8 - 101.0%
Endotoxin (ChP)	< = 10 EU/g
Calcium (ChP/JP)	Passes Test
Chloride (USP/EP/JP/ChP)	< = 6 ppm
Color (USP/JP/ChP)	Passes Test
Esters (EP)	Passes Test
Fatty Acids and Esters	Passes Test
Fatty Acids and Esters (USP)	Passes Test
Halogenated Compounds (EP/ChP)	< = 30 ppm
Limit of Chlorinated Compounds (USP)	< = 30ppm of Cl
Heavy Metals (Pb) (ChP/JP)	< = 2 ppm
Identification, IR (USP-A/EP-B/ChP/JP)	Conforms to Reference Standard
Identification C (USP)	Conforms to Reference Standard
Iron (ChP)	< = 0.5 ppm
Microbial Content	TAMC (ChP) < 50 CFU/g TYMC (ChP) < 50 CFU/g Escherichia Coli (ChP) Absent/g

ANALYSIS	SPECIFICATIONS
Purity	> = 99.7%
Diethylene Glycol (USP-B/EP/ChP/JP)	< = 0.025%
Ethylene Glycol (USP-B/ChP/JP)	< = 0.025%
1,2-propylene glycol (ChP)	< = 0.1%
Any Individual Unspecified Impurity with RRT < RRT of Glycerin (EP)	< = 0.1%
Any Individual Unspecified Impurity with RRT > RRT of Glycerin (EP)	< = 0.1%
Any Individual Unspecified Impurity (USP/ChP/JP)	< = 0.1%
Total Impurities (USP/ChP/JP)	< = 0.5%
Residual Solvents Methanol	< = 3000 ppm
Readily Carbonizable Substances (ChP/JP)	Passes Test
Refractive Index, 20 °C (EP-A/JP/ChP)	1.470 - 1.475
Residue on Ignition / Sulfated Ash (USP/EP/ChP/JP)	< = 0.01%
Specific Gravity, 25 °C (USP)	> = 1.249
Specific Gravity, 20 °C (EP-C/JP/ChP)	1.258 - 1.268
Sugars (EP/ChP)	Passes Test
Sulfate (USP/ChP/JP)	< = 20 ppm
Water, KF (USP/EP/ChP/JP)	< = 2.0%

*Bioburden and Endotoxin Tested

Refer to page 2 for additional product details

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General Product Overview

Glycerin, Synthetic, USP, EP, BP, JP, ChP, 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.](#)