

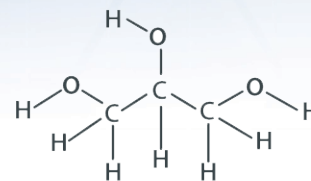
## Synthetic Glycerin, USP, EP, Parenteral Grade, GMP Excipient Grade

### INTENDED FOR USE AS A PARENTERAL EXCIPIENT

Synthetic Parenteral Glycerin (Glycerol) is a fully synthetic, parenteral grade, suitable for use in insulin manufacturing and other critical cGMP manufacturing applications and pharmaceutical preparations.

**Lead Time: Please Inquire**

**Minimum Order Quantity: Please Inquire**



**Formula:** C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>

**F.W.:** 92.1 g/mol

**CAS #:** 56-81-5

### BIO EXCIPIENT GRADE | Product Code: GLYS-3151

C<sub>3</sub>H<sub>8</sub>O<sub>3</sub> • F.W. 92.1 g/mol. • CAS# 56-81-5

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

### USP Compendia

ANALYSIS		SPECIFICATIONS
Assay (Dried Basis)		99.0 to 101.0%
Chloride		≤ 10ppm
Color		Passes Test
Fatty acid and Esters		Passes Test
Identification	Identification A IR	Conforms with reference standard ≤ 0.025% <sup>1</sup> ≤ 0.025% <sup>1</sup> Passes Test
	Identification B Diethylene glycol	
	Identification B ethylene glycol	
	Identification C by GC	
Limit of Chlorinate Compounds		≤ 30ppm of Cl
Related Compounds	Any Individual Impurity	≤ 0.1%
	Total Impurities	≤ 0.5% <sup>1</sup>
Residue of Ignition		≤ 0.01%
Specific gravity (at 25.0°C)		≥ 1.249
Sulfate		≤ 20ppm
Water Content		≤ 2.0% <sup>1</sup>



<sup>1</sup>stringent specification

ANALYSIS		SPECIFICATIONS
Aldehydes		≤ 10ppm
Acidity or alkalinity		Passes Test
Appearance		Clear, colorless, or almost colorless viscous liquid
Appearance of solution		Solution is clear, colorless
Assay (Dried Basis)		99.0 to 101.0% <sup>1</sup>
Chlorides		≤ 10ppm
Esters		Passes Test
Halogenated compounds		≤ 35ppm
Identification	Identification A, Refractive Index	1.470 – 1.475
	Identification B, IR	Conforms with reference standard
	Identification C, Relative density	1.258 - 1.268
Related substances	Impurity A	≤ 0.025% <sup>2</sup>
	Any other Individual impurity	≤ 0.1%
	Total impurities	≤ 0.5%
Sugars		Passes Test
Sulfated Ash		≤ 0.01%
Water		≤ 2.0%

<sup>1</sup>USP Specification  
<sup>2</sup>Stringent specification

### General Product Description:

Synthetic Glycerin is produced at our cGMP platform in India and then shipped to and fully retested and packaged at our sites in Rensselaer, NY and Bangor PA, USA.

- Synthetic Glycerin is a Clear Liquid product.
- Molecular Formula: C<sub>3</sub> H<sub>8</sub> O<sub>3</sub>
- Molecular Weight: 92.09 g/mol
- CAS Number: 56-81-5
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- Synthetic Glycerin GLYS-3151 at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Synthetic Glycerin manufactured at our cGMP platform in India and any raw materials used in the manufacture of Synthetic Glycerin at BioSpectra are not subject to genetic modification.
- Synthetic Glycerin is further purified at our site in Canada, Dextran Products apart of the BioSpectra Organization
- Synonyms: Glycerol, Glycerolum, Glicerol, Glyzerin, 1,2,3-Propantriol, Glycerinester, Pfl.

### GMP Compliance:

Bio Excipient Grade Synthetic Glycerin, GLYS-3151 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Synthetic Glycerin is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

### Retest Date:

The recommended retest period for Synthetic Glycerin is two years from the date of manufacture.

### Storage and Shipping Conditions:

Ship and store in ambient temperature.

### Package Sizes:

6x1L, 4x 3.78L, 10L, 200L and 1000 liter

(Please contact us for more specific information about your package size and Chain of Custody.)

### Country of Origin:

India