

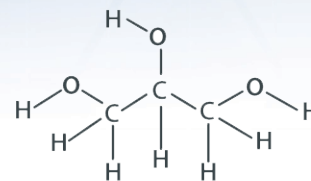
Synthetic Glycerin, USP, EP, JP and Ch.P., Parenteral Grade, GMP Excipient Grade

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: C₃H₈O₃

F.W.: 92.1 g/mol

CAS #: 56-81-5

BIO EXCIPIENT GRADE | Product Code: GLYS-3150

C₃H₈O₃ • 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% ¹ ≤ 0.025% ¹ 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% ¹
Residue of Ignition		≤ 0.01%
Specific gravity (at 25.0°C)		≥ 1.249
Sulfate		≤ 20ppm
Water Content		≤ 2.0% ¹



¹stringent specification

Synthetic Glycerin GLYS-3150

EP Compendia

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% ¹
Chlorides		≤ 10ppm
Esters		Passes Test
Halogenated compounds		≤ 35ppm
Identification	Identification A, Refractive Index Identification B, IR Identification C, Relative density	1.470 – 1.475 Conforms with reference standard 1.258 - 1.268
Related substances	Impurity A Any other Individual impurity Total impurities	≤ 0.025% ² ≤ 0.1% ≤ 0.5%
Sugars		Passes Test
Sulfated Ash		≤ 0.01%
Water		≤ 2.0%

¹USP Specification
²Stringent specification

JP Compendia

ANALYSIS		SPECIFICATIONS
Acidity or Alkalinity		Passes Test
Acrolein, glucose, or other reducing substances		Passes Test
Ammonium		Passes Test
Appearance		Clear, colorless, or almost colorless viscous liquid
Arsenic		≤ 0.3ppm ²
Assay (Dried Basis)		99.0 to 101.0% ¹
Calcium		Passes Test
Chloride		≤ 10ppm
Color		Passes Test
Fatty Acids or Esters		Passes Test
Heavy Metals		≤ 2ppm ²
Identification, IR		Conforms with reference standard
Readily carbonizable substances		Passes Test
Related Substances	Diethylene glycol Ethylene glycol Any other individual impurity Total impurities	≤ 0.025% ² ≤ 0.025% ² ≤ 0.1% ≤ 0.5%
Refractive Index @20°C		≥1.470
Residue on Ignition		≤ 0.01%
Specific Gravity @20°C		≥1.258
Sulfate		≤ 20ppm
Water		≤ 2.0%

¹USP Specification
²Stringent specification


Synthetic Glycerin GLYS-3150

ANALYSIS		SPECIFICATIONS
Acidity or Alkalinity		Passes Test
Aldehydes and Related Substances		Passes Test
Ammonium		Passes Test
Appearance		Clear, colorless, or almost colorless viscous liquid
Arsenic		≤ 0.3ppm
Assay (Dried Basis)		99.0 to 101.0% ¹
Bacterial Endotoxin		≤ 10 EU/g
Calcium		Passes Test
Chloride		≤ 6ppm
Color		Passes Test
Fatty acid and esters		Passes Test
Halogenated Compounds		≤ 30ppm
Heavy Metals		≤ 2ppm
Identification A, IR		Conforms with reference standard
Iron		≤ 0.5ppm
Microbial Limit	Escherichia coli TAMC TYMC	Absent/per g ≤ 100CFU/g ² ≤ 100CFU/g
Readily carbonizable substances		Passes Test
Refractive Index		1.470 -1.475
Relative Density		1.258 – 1.268
Related Substances	Diethylene glycol	≤ 0.025%
	Ethylene glycol	≤ 0.025%
	1,2-Propylene glycol	≤ 0.1%
	Any other individual impurity	≤ 0.1%
	Total impurities	≤ 0.5%
Residue of Ignition		≤ 2mg
Specific gravity (at 25.0°C)		≥ 1.249
Sugars		Passes Test
Sulfates		≤ 20ppm
Water		≤ 2.0%

¹USP Specification
²Stringent specification

ANALYSIS		SPECIFICATIONS
Dihydroxyacetone		≤ 5ppm
Formaldehyde		≤ 5ppm
Glyceraldehyde		≤ 5ppm
Hydroxyacetone		≤ 5ppm
Methanol		≤ 3000ppm
Total Bioburden		≤ 100CFU/g

Synthetic Glycerin GLYS-3150

 Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH-Q7 Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).

LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

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: $C_3H_8O_3$
- 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-3150 at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Synthetic Glycerin is synthesized 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-3150 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