



Certificate of Analysis

1 Reagent Lane
Fair Lawn, NJ 07410
201.796.7100 tel
201.796.1329 fax

Thermo Fisher Scientific's Quality System has been found to conform to Quality Management System
Standard ISO9001:2015 by SAI Global Certificate Number CERT – 0120632

This is to certify that units of the lot number below were tested and found to comply with the specifications of the grade listed. Certain data have been supplied by third parties. Thermo Fisher Scientific expressly disclaims all warranties, expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. Products are for research use or further manufacturing. Not for direct administration to humans or animals. It is the responsibility of the final formulator and end user to determine suitability based upon the intended use of the end product. Products are tested to meet the analytical requirements of the noted grade. The following information is the actual analytical results obtained.

Catalog Number	G30	Quality Test / Release Date	05/20/2019
Lot Number	191432		
Description	GLYCERIN, USP/FCC/EP/BP		
Country of Origin	United States	Suggested Retest Date	May/2021
Chemical Origin	Plant		
BSE/TSE Comment	No animal products are used as starting raw material ingredients, or used in processing, including lubricants, processing aids, or any other material that might migrate to the finished product.		
Chemical Comment	Glycerin does not contain potential allergens, including peanuts, milk, egg, wheat, gluten, or soybean. In addition, it does not contain melamine, phthalates or Bis-Phenol A. The glycerin is solely sourced from vegetable oils, which can include oil from GMO oilseeds. However, GMO genetic materials are not expected to be present in the refined glycerin made from the highly refined oils.		

British Pharmacopeia Grade			
Result Name	Units	Specifications	Test Value
APPEARANCE		REPORT	Clear Colorless Liquid
ALDEHYDES	ppm	<= 10	<10
ACIDITY - ALKALINITY	PASS/FAIL	= PASS TEST	PASS TEST
APPEARANCE OF SOLUTION	REPORT	= CLEAR AND COLORLESS	CLEAR AND COLORLESS
ASSAY	%	Inclusive Between 98.0 - 101.0	99.7
CHLORIDES	ppm	<= 10	<10
ESTERS	PASS/FAIL	= PASS TEST	PASS TEST
HALOGENATED COMPOUNDS (AS CL)	ppm	<= 35	<35
HEAVY METALS	ppm	<= 5	<5
IDENTIFICATION (ALL LISTED)	PASS/FAIL	= PASS TEST	PASS TEST
IMPURITY A	%	<= 0.1	<0.1
OTHER IMPURITIES (RT < GLYCEROL)	%	<= 0.1	<0.1
REFRACTIVE INDEX @ 20 DEG C		Inclusive Between 1.470 - 1.475	1.474
RESIDUAL SOLVENTS	CONFORMS	= CONFORMS	CONFORMS
SUGARS	PASS/FAIL	= PASS TEST	PASS TEST
SULFATED ASH	%	<= 0.01	0.001
WATER	%	<= 2.0	<0.2
TOTAL OF ALL IMPURITIES (RT>GLYCEROL)	%	<= 0.5	<0.5

Note: The data listed is valid for all package sizes of this lot of this product, expressed as an extension of this catalog number listed above. If there are any questions with this certificate, please call at (800) 227-6701.

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EP Grade			
Result Name	Units	Specifications	Test Value
APPEARANCE		REPORT	Clear Colorless Liquid
OTHER IMPURITIES (RT < GLYCEROL)	%	<= 0.1	<0.1
ACIDITY OR ALKALINTY	PASS/FAIL	= PASS TEST	PASS TEST
ALDEHYDES	ppm	<= 10	<10
TOTAL OF ALL IMPURITIES (RT>GLYCEROL)	%	<= 0.5	<0.5
APPEARANCE OF SOLUTION	REPORT	= CLEAR AND COLORLESS	CLEAR AND COLORLESS
ASSAY	%	Inclusive Between 98.0 - 101.0	99.7
CHLORIDES	ppm	<= 10	<10
BACTERIAL ENDOTOXINS	REPORT	= REPORT	<0.64 EU/ ML
ESTERS	PASS/FAIL	= PASS TEST	PASS TEST
HALOGENATED COMPOUNDS (AS CL)	ppm	<= 35	<35
HEAVY METALS	ppm	<= 5	<5
IDENTIFICATION (ALL LISTED)	PASS/FAIL	= PASS TEST	PASS TEST
IMPURITY A	%	<= 0.1	<0.1
REFRACTIVE INDEX @ 20 DEG C		Inclusive Between 1.470 - 1.475	1.474
RESIDUAL SOLVENTS	CONFORMS	= CONFORMS	CONFORMS
SUGARS	PASS/FAIL	= PASS TEST	PASS TEST
SULFATED ASH	%	<= 0.01	0.001
WATER	%	<= 2.0	<0.2

FCC Grade			
Result Name	Units	Specifications	Test Value
APPEARANCE		REPORT	Clear Colorless Liquid
LEAD (Pb)	MG/KG	<= 1	1
IGNITION RESIDUE	%	<= 0.01	0.001
IDENTIFICATION (ALL LISTED)	PASS/FAIL	= PASS TEST	PASS TEST
FATTY ACIDS ESTERS	PASS/FAIL	= PASS TEST (LIMIT 0.1% AS BUTYRIC ACID)	PASS TEST (LIMIT 0.1% AS BUTYRIC ACID)
CARBONIZABLE SUBSTANCES	PASS/FAIL	= PASS TEST	PASS TEST
CHLORINATED COMPOUND	%	<= 0.003	<0.003
SPECIFIC GRAVITY		>= 1.249	1.262
ASSAY	%	Inclusive Between 95.0 - 100.5	99.6
COLOR	PASS/FAIL	= PASS TEST	PASS TEST

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USP Grade			
Result Name	Units	Specifications	Test Value
APPEARANCE		REPORT	Clear Colorless Liquid
CHLORINE COMPOUNDS	%	<= 0.003	<0.003
CHLORIDE	%	<= 0.001	<0.001
COLOR	PASS/FAIL	= PASS TEST	PASS TEST
DIETHYLENE GLYCOL & RELATED INDIVIDUAL	%	<= 0.1	<0.1
DIETHYLENE GLYCOL & RELATED TOTAL	%	<= 1.0	<1.0
ASSAY	%	Inclusive Between 99.0 - 101.0	99.7
IDENTIFICATION (ALL LISTED)	PASS/FAIL	= PASS TEST	PASS TEST
IGNITION RESIDUE	%	<= 0.01	0.001
USP PROTOCOL REQUIRED	PASS/FAIL	= PASS TEST	PASS TEST
RESIDUAL SOLVENTS	Meets Requirements	= MEETS REQUIREMENTS	MEETS REQUIREMENTS
FATTY ACID ESTERS	PASS/FAIL	= PASS TEST	PASS TEST
SPECIFIC GRAVITY		>= 1.249	1.262
SULFATE (SO ₄)	%	<= 0.002	<0.002
WATER	%	<= 5.0	<0.5
HEAVY METALS (as Pb)	ppm	<= 5	<5

Residual Solvents	No Class 1 or 3 Residual Solvents are used in the processing of Glycerin. Class 2 Methanol is used as a reactant to manufacture Glycerin but is removed in subsequent manufacturing processes to typically below 1 ppm. This is well below the 3000 ppm recommended maximum concentration in drug products.
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Jerisa Bailey-Wyche

Quality Assurance Specialist - Certificate of Analysis Bridgewater

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