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	G31	Quality Test / Release Date	05/26/2020
Lot Number			
Description	GLYCERIN, USP/FCC		
Country of Origin	Malaysia	Suggested Retest Date	May/2022
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.		
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.		

FCC Grade

Result Name	Units	Specifications	Test Value
APPEARANCE		REPORT	Clear Colorless Liquid
ASSAY	%	Inclusive Between 95.0 - 101.0	99.7
CARBONIZABLE SUBSTANCES	PASS/FAIL	= PASS TEST	PASS TEST
CHLORINATED COMPOUND	%	<= 0.003	<0.003
COLOR	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)
IDENTIFICATION (ALL LISTED)	PASS/FAIL	= PASS TEST	PASS TEST
IGNITION RESIDUE	%	<= 0.01	0.002
LEAD (Pb)	MG/KG	<= 1	<1
SPECIFIC GRAVITY		>= 1.259	1.262
WATER	%	<= 1.0	0.09

USP Grade

Result Name	Units	Specifications	Test Value
APPEARANCE		REPORT	Clear Colorless Liquid
ASSAY	%	Inclusive Between 99.0 - 101.0	99.8
CHLORIDE	ppm	<= 10	<10
CHLORINE COMPOUNDS	ppm	<= 30	<30
COLOR	PASS/FAIL	= PASS TEST	PASS TEST
DIETHYLENE GLYCOL	%	<= 0.1	<0.10

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.
*Based on suggested storage condition.

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

ETHYLENE GLYCOL	%	<= 0.1	<0.10
FATTY ACID ESTERS	PASS/FAIL	= PASS TEST	PASS TEST
IDENTIFICATION A	PASS/FAIL	= PASS TEST	PASS TEST
IDENTIFICATION C	PASS/FAIL	= PASS TEST	PASS TEST
IGNITION RESIDUE	%	<= 0.01	0.002
RESIDUAL SOLVENTS	PASS/FAIL	= PASS TEST	PASS TEST
SPECIFIC GRAVITY		>= 1.249	1.262
SULFATE (SO4)	ppm	<= 20	<20
USP INDIVIDUAL IMPURITY	%	<= 0.1	<0.1
USP PROTOCOL REQUIRED	PASS/FAIL	= PASS TEST	PASS TEST
USP TOTAL IMPURITY	%	<= 1.0	<1.0
WATER	%	<= 5.0	<0.5

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.

Julian Burton

Julian Burton - Quality Control Manager - Bridgewater

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.
*Based on suggested storage condition.