



TECHNICAL DATA SHEET

151333-TDS-ENG-2021

GLICERINA FARMACEUTICA EP		
DESCRIPTION DCI: GLYCEROL		DESCRIPTION DOE: GLICERINA
CAS N°: 56-81-5	EC N°: 200-289-5	AEMPS CODE: ---
MOL. WEIGHT: 92.09	MOL. FORMULA: C3H8O3	ARTICLE CODE: 151333

ATTRIBUTES	SHOULD BE
Appearance	Syrupy liquid, unctuous to the touch, colourless or almost colourless, clear, very hygroscopic
Solubility	Miscible with water and with ethanol (96 %), slightly soluble in acetone, practically insoluble in fatty oils and in essential oils
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
Acidity or alkalinity	=< 0.2 mL of 0.1 M NaOH
Refractive index	1.470 - 1.475
Aldehydes	=< 10 ppm
Esters	=> 8.0 mL of 0.1 M HCl
Impurity A and related substances	
Impurity A	=< 0.1 %
Any other impurity eluting before glycerol	=< 0.1 %
Total impurities eluting after glycerol	=< 0.5 %
Halogenated compounds	=< 35 ppm
Sugars	Complies
Chlorides	=< 10 ppm
Water	=< 2.0 %
Sulfated ash	=< 0.01 %
Assay	98.0 - 101.0 %
Residual solvents	
Methanol	=< 300 ppm

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Keep container in a well ventilated place. Store at room temperature. Protect against direct sunlight.

REMARKS

The product is manufactured from vegetable raw materials.

The product does not contain any ingredients that are derived from GM sources. However relevant thresholds for adventitious are technically unavoidable cross-contamination as laid down in 1829/2003/EC are accepted. Moreover, the above-mentioned material has not o been labeled according to Regulation (EC) 1830/2003/EC concerning traceability and labeling of food and feed products manufactured from genetically modified organisms.

The product complies with the microbiological purity criteria of European Pharmacopoeia monographs EP 2.6.12 and EP 2.6.13.



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The product is food approved according to EU Regulation 231/2012 and EC Regulation 1333/2008.