

GLICERINA FARMACEUTICA (EUR. PH.) (EUR-GMP)

PRODUCT CODE: 151333	CAS Nº: 56-81-5	ANALYSIS Nº: 051/25
MANUFACTURER BATCH: VE6C250202	CERTIFICATE ID: 45.387	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 03/02/2025	
METAPH BATCH: 0040325	EXPIRY DATE: 03/02/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Clear, colourless or almost colourless, very hygroscopic, syrupy liquid, unctuous to the touch	Clear, colourless, very hygroscopic, syrupy liquid, unctuous to the touch
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Acidity or alkalinity	=< 0.2 mL of 0.1 M NaOH	0.08 mL of 0.1M NaOH
Refractive index	1.470 - 1.475	1.473
Aldehydes	=< 10 ppm	< 10 ppm
Esters	=> 8.0 mL of 0.1 M HCl	8.9 mL of 0.1M HCl
Impurity A and related substances		
Impurity A	=< 0.1 %	0.06 %
Any other impurity eluting before glycerol	=< 0.1 %	Not Detected
Total impurities eluting after glycerol	=< 0.5 %	0.4 %
Halogenated compounds	=< 35 ppm	< 30 ppm (*)
Sugars	Complies	Complies
Chlorides	=< 10 ppm	< 10 ppm
Water	=< 2.0 %	0.7 %
Sulfated ash	=< 0.01 %	0.00 %
Assay	98.0 - 101.0 %	100.2 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

(*) Data adapted from the certificate of analysis of the manufacturer.

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

STORAGE

Analysis date: 18/03/2025
 Signature: Cristina Borrell Olea (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000907
 OLEON
 RUE DE LES RIVES DE L OISE
 60280
 VENETTE(França)





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

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