

CERTIFICATE OF ANALYSIS

Batch: 25B12-H500705323

Product: Glycerolum Ph. Eur. – Glycerine – Glycérine – 5L

Production date: 12 FEB 2025

Expiry date: 17 SEP 2026

Analysed according to: Ph. Eur. 11.0

Analysis performed on: 17 FEB 2025

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Appearance		
Appearance	Clear, colourless or almost colourless, very hygroscopic syrupy liquid, unctuous to the touch. Miscible with water and with ethanol 96%, slightly soluble with acetone, practically insoluble in fatty oils and essential oils	Complies
Identifications		
Identification A	Complies	Complies
Identification B	Complies	Complies
Other tests		
Acidity or Alkalinity	Max 0.2	<0.1 mL NaOH 0.1M
Refractive index	1.470 – 1.475	1.471
Aldehydes	Max 10	<10 µg/g
Esters	Min 8.0	9.2 mL HCl 0.1M
Impurity A and related substances	Complies	Complies
Impurity A	Max 0.1	<0.05%
Any other impurity with RT less than RT of glycerol	Max 0.1	<0.05%
Total impurities with RT less than RT of glycerol	Max 0.5	<0.05%
Halogenated compounds	Max 35	<35 µg/g
Sugars	Complies	Complies
Chlorides	Max 10	<10 µg/g
Water	Max 2.0	0.2%
Sulphated ash	Max 0.01	<0.01%
Content (anhydrous substance)	98.0 – 101.0	100.1%



Conclusion:

The batches comply with the specifications of the performed analysis and is thereby released.

BATCH RELEASED BY:

Dr. Apr. Ammar Kurdi

Responsible Pharmacist

Release date:

05 MAART 2025

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