

CERTIFICATE OF ANALYSIS

Product name: GLICEROL

Inspection No: I07665/0921/536

Batch No: 088597 **Batch size:** 1 700 x 1 kg

Expiry date: 27.08.2023

Analyzed according to: Ph. Eur. 0497

	Requirements:	Results:
Appearance	syropy liquid, unctuous to the touch, colourless or almost colourless, clear, very hygroscopic	complies
Solubility	miscible with water and with ethanol (96 per cent), slightly soluble in acetone, practically insoluble in fatty oils and in essential oils	complies
Identification	complies with Ph. Eur.	complies
Appearance of solution	solution is clear and colourless	complies
Acidity or alkalinity	not more than 0,2 ml 0,1M/L NaOH	0,1 ml
Refractive index	1,449 - 1,455	1,454
Aldehydes	not more than 10 ppm	<10 ppm
Esters	not less than 8,0 ml 0,1M/L HCL	9,3 ml
Impurity A and related substances		complies
impurity A:	not more than 0,1 %	<0,1 %
any other impurity with a retention time less than the retention time of glycerol:	not more than 0,1 %	<0,1 %
total of all impurities with retention times greater than the retention time of glycerol:	not more than 0,5 %	<0,5 %
Halogenated compounds	not more than 30 ppm	<30 ppm
Sugars	complies with Ph. Eur.	complies
Chlorides	not more than 10ppm	<10 ppm
Water	12,0 - 16,0 %	12,6 %
Sulfated ash	not more than 0,01 %	0,00 %
Assay	83,5 - 88,5 % [m/m]	86,6 %

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The product conforms to Ph. Eur. 0497

Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

Approved by: MVDr. Zdenka Borská, QP

Date and signature: 4. 10. 2021 *Bz*