





Packaging for pharmaceutical and cosmetic use

Raw materials for pharmaceutical cosmetic and food use

Equipment and furniture for galenic laboratory

## CERTIFICATE OF ANALYSIS

Product

1202A Vegetable glycerol EP USP

LIMITS

Batch Number R1201173 - 04051

Manufacturer

Retest date 14/04/2013

## **TECHNICAL DATA SHEET**

**PRODUCT** VEGETABLE GLYCEROL EP USP CHEMICAL NAME 1,2,3-propanetriol FARMADENT d.o.o. INCI NAME Glycerin Minarikova ul. 6 CAS NUMBER 56-81-5 2000 Maribo MOLECULAR FORMULA C3H8O3 DRAGO MOLECULAR WEIGHT 92.1 OTHER NAMES Glycerin; Trihydroxypropane jema: 277.2012 ORIGIN Vegetable TYPE OF PRODUCT AND USE Pharmaceutical and food use (E422) Pregledal: N ex) mag, farm., spec. **APPEARANCE** Clear and colourless, syrupy liquid, very hygroscopic (20°C) ODOUR SOLUBILITY Soluble in water, alcohol; slightly soluble in acetone STORAGE Store at room temperature, in a cool and aerated place. **PROPERTIES** Antimicrobial preservative; solvent and cosolvent; emollient; humectant; sweetening agent; tonicity agent. In topical pharmaceutical formulations and cosmetics, glycerin is used primarly for its humectant and **APPLICATIONS** emollient properties; glycerin is also used as a solvent or cosolvent in creams and emulsions. Glycerin is additionally used in aqueous and nonaqueous gels and also as an additive in patch applications. In oral solutions, glycerin is used as a solvent, sweetening agent, antimicrobial preservative and viscosity-increasing agent. It is also used as a plasticizer of gelatin in the production of soft-gelatin capsules

and gelatin suppositories; it is also used in film coatings. Antimicrobial preservative < 20%; Emollient <= 30%; Gel vehicle, aqueous 5-15%; Gel vehicle, RECOMMENDED DOSAGE nonaqueous: 50-80%; Humectant <= 30%

ASSAY	Glycerol content >= 99,70% w/w	99,88%
	Complies (USP)	Complies
IDENTITY	Identification A (Refractive index): conform	Conform
	Identification B (IR): conform	Conform
	Identification C (Nitric acid): conform	Conform
	Identification D (Acroleine test): conform	Conform
	Identification B (USP): conform	Conform
	Identification C (USP): conform	Conform
COLOUR	APHA color: <= 10	7,5
ODOUR	Complies	Complies
DENSITY	>= 1,2490 Kg/m3 at 25°C (USP)	1,2615 kg/m3
APPEARANCE OF SOLUTION	Conform (EP)	Conform
REFRACTIVE INDEX	1,473-1,474 (20°C)	1,474
RESIDUE ON IGNITION	<= 0,01% (USP)	< 0,01%
WATER	<= 0,3% w/w	0,08% w/w
SULFATED ASH	<= 0,01% w/w (EP)	< 0,01% w/w
HEAVY METALS	Total heavy metals <= 5 ppm (EP)	< 5 ppm
	<= 5 mcg/g (USP)	< 5 mcg/g
SULFATES	<= 0,002% w/w (USP)	< 0.002%

<= 10 ppm (EP) < 10 ppm ACIDITY/ALCALINITY Acidity (EP): <= 0,20 ml NaOH 0,1 M 0,05 ml Farmalabor is a pharmaceutical company authorized by ASFA (Agenzia Italiana del Farmaco) for repackaging and batich release of active pharmaceutical ingredients in compliance with the Article 47 of Directive 2001/83/EC

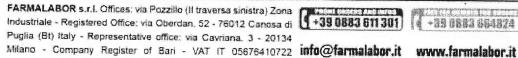
<= 0,002% w/w (USP)

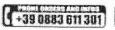
<= 10 ppm (EP)

The Company's Quality is recognized by certification: ISO 9001:2008 ISO14:001:2004

**CHLORIDES** 

**ANALYSIS** 

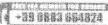




< 0,002%

< 0,001%

**RESULTS** 







Farmalabor TECH

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**Product** 

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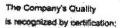
Manufacturer

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ANALYSIS	LIMITS	RESULTS	
ACIDITY/ALCALINITY	Complies with EP	Complies	
	Acidity (APAG) <= 0,08 meq/100 g	0,02 meq/100 g	
	Alkalinity (EP) <= 0,00 ml NaOH 0,1 M	0,00 ml	
FATTY ACIDS AND ESTERS	<= 1 ml 0,5N NaOH (USP)	< 1 ml	
ESTERS	>= 8 ml HCl 0,1M (EP)	> 8 ml	
RELATED SUBSTANCES	Impurity A and related substances: conform	Conform	
	- impurity A (DEG) <= 0,1%	< 0,1%	
	- any other impurityeluating before Glycerol: <= 0,1%	< 0,1%	
	- total impurities eluating after Glycerol: <= 0,5%	< 0.5%	
	DEG and related compounds (USP): conform	Conform	
	- any individual impurity (excluding DEG) <= 0,1%	< 0.1%	
	- total impurities, including DEG: <= 1,0%	< 1,0%	
	- Diethylene glycol <= 0,025%	< 0.025%	
	- Ethylene glycol <= 0,025%	< 0,025%	
ALDEHYDES	<= 10 ppm (EP)	< 10 ppm	
SUGARS	Conform (EP)	Conform	
IMPURITIES	Chlorinated compounds (USP) <= 0,003% w/w (USP)	< 0,003%	
	Halogenated compounds <= 30 ppm (EP)	< 30 ppm	
VOLATILE ORGANIC IMPURITIES	Conform	Conform	
RESIDUAL SOLVENTS	The product is in compliance with the guideline CPMP/ICH/283/95	Conform	
MICROBIOLOGICAL CONTROL	The product complies with the microbiological purity criteria of European Pharmacopoeia monographs EP 2.6.12 and EP 2.6.13	Conform	
NOTES			
NOTES	GMO free (Reg. EC 1829-1830/2003); suitable for food use (E 422)		
	to EU Directive 2008/84/EC and Regulation 1333/2008/EC. The pr	roduct complies with F	FDA §182.1320 on
DUADAMACODOFIA	the GRAS status (Generally Recognized as Safe).		
PHARMACOPOEIA	Complies with EP VII ed. (2011), USP-NF	and the second	

All specifications are as provided by the original manufacturer. They do not imply any exemption from identifying and inspecting the product before its use, the final user being fully responsible for the adoption and the correct usage of the product.

Technical director Dr. Giovanni Summonte



ISO 9001:2008 15014:001:2004

