



Farmalabor recal

Packaging for pharmaceutical and cosmetic use

Raw materials for pharmaceutical cosmetic and food use

Equipment and furniture for galenic laboratory

FARMADENT d.o.o.

Minarikova ul. 6

2000 Maribor

Prejel: FUJ8

Pregledal: MAR

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## CERTIFICATE OF ANALYSIS

1202A Vegetable glycerol EP USP

Batch Number P1202060-000

Manufacturer

Retest date 03/03/2014

## **TECHNICAL DATA SHEET**

**PRODUCT** VEGETABLE GLYCEROL EP USP CHEMICAL NAME 1,2,3-propanetriol INCI NAME Glycerin CAS NUMBER 56-81-5 MOLECULAR FORMULA C3H8O3 MOLECULAR WEIGHT 92,1 OTHER NAMES Glycerin; Trihydroxypropane ORIGIN Vegetable TYPE OF PRODUCT AND USE

**APPEARANCE** SOLUBILITY STORAGE **PROPERTIES** 

Pharmaceutical and food use (E422)

Clear and colourless, syrupy liquid, very hygroscopic (20°C) Soluble in water, alcohol; slightly soluble in acetone Store at room temperature, in a cool and aerated place.

Technological properties: antimicrobial preservative; solvent and cosolvent; emollient; humectant; sweetening agent; tonicity agent. Therapeutic properties: glycerol is an osmotic dehydrating agent with hygroscopic and lubricating properties; when given orally, it exerts an emollient, slightly laxative effect; when administered rectally, it can promote faecal evacuation in the management of constipation; it usually acts within 15 to 30 minutes. The glycerol exerts an osmotic effect which is responsible for increasing the plasma osmolality, resulting in the movement of water by osmosis from the extravascular spaces into the plasma and, consequently, in the reduction of intra-ocular pressure; glycerol has also been given orally to reduce intracranial pressure in various pathological situations.

In topical pharmaceutical formulations and cosmetics, glycerin is used primarly for its humectant and 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. For its pleasant taste and for its high viscosity, it is used both as a sweetener and as an active ingredient in syrups and tablets.

RECOMMENDED DOSAGE

**APPLICATIONS** 

As a laxative: in adults and children older than 6 years, the usual dose of glycerol is 2-3 g when administered rectally as a suppository or 5-15 ml when administered as enema (6-9 g each micro-enema, often in association with starch and mallow and chamomile liquid extracts); for younger children, the usual doses are halved. Antimicrobial preservative < 20%; Emollient <= 30%; Gel vehicle, aqueous 5-15%; Gel vehicle, nonaqueous: 50-80%; Humectant <= 30%.

ANALYSIS	LIMITS	RESULTS
ASSAY	Glycerol content >= 99,70% w/w	
IDENTITY	Conform (USP)  Identification A (Refractive index): conform  Identification B (IR): conform  Identification C (Nitric acid): conform  Identification D (Evaporating test): conform  Identification B (USP): conform  Identification C (USP): conform  Complies  Identification C (USP): conform  Complies*  Results APHA color: <= 10  Conform  Y  >= 1,2490 g/ml at 25°C (USP)  RANCE OF SOLUTION  Conform (EP)  1,2615 g/ml	Complies Complies
		Complies Complies
COLOUR ODOUR DENSITY APPEARANCE OF SOLUTION		Complies* 5,0 Complies 1,2615 g/ml
REFRACTIVE INDEX		a statement of the stat

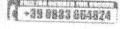
Farmerabor is a pharmaceutical company authorized by AsFA (Agenzia Italiana del Farmaco) for repackaging and batich release of active pharmaceutical ingredients in compliance with the Article 47 of Directive 2001/83/EC

is recognized by certification: ISO 9001:2008 15014:001:2004



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Manufacturer

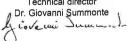
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ANALYSIS	LIMITS	RESULTS
RESIDUE ON IGNITION	<= 0.01% (USP)	< 0,01%
WATER	<= 0,3% w/w	0,07%
SULFATED ASH	<= 0.01% w/w (EP)	< 0,01%
HEAVY METALS	Total heavy metals <= 5 ppm (EP)	< 5 ppm *
TEAV I WE TAES	<= 5 mcg/g (USP)	< 5 mcg/g *
SULFATES	<= 0.002% w/w (USP)	< 0,002% *
CHLORIDES	<= 0,001% w/w (USP)	< 0,001%
SHEORIDES	<= 10 ppm (EP)	< 10 ppm
ACIDITY/ALCALINITY	Alkalinity (EP) <= 0,00 ml NaOH 0,1 M	0,00 ml
ACIDIT I/ALCALINITI	Acidity (EP): <= 0,20 ml NaOH 0,1 M	0,05 ml
	Conform (EP)	Complies
	Acidity (APAG) <= 0,08 meq/100 g	0,02 meg/100 g
TATTY ACIDS AND ESTEDS	<= 1 ml 0,5N NaOH (USP)	< 1 ml
FATTY ACIDS AND ESTERS	>= 8,0 ml HCl 0,1M (EP)	> 8,0 ml
ESTERS	Impurity A and related substances: conform	Complies
RELATED SUBSTANCES	- impurity A (DEG) <= 0,1%	< 0.1%
	- any other impurityeluating before Glycerol: <= 0,1%	< 0,1%
		< 0,5%
	- total impurities eluating after Glycerol: <= 0,5%	Complies
	DEG and related compounds (USP): conform	< 0,1%
	- any individual impurity (excluding DEG) <= 0,1%	< 1.0%
	- total impurities, including DEG: <= 1,0%	< 0,025%
	- Diethylene glycol <= 0,025%	< 0,025%
	- Ethylene glycol <= 0,025%	< 10 ppm *
ALDEHYDES	<= 10 ppm (EP)	
SUGARS	Conform (EP)	Complies < 0,003%
IMPURITIES	Chlorinated compounds (USP) <= 0,003% w/w (USP)	
	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	Complies
MICROBIOLOGICAL CONTROL	The product complies with the microbiological purity criteria of European Pharmacopoeia monographs EP 2.6.12 and EP 2.6.13	Complies
NOTES		
	*Periodically measured value.	
NOTES	GMO free (Reg. EC 1829-1830/2003); suitable for food use (E 422): the product is food approved according to EU Directive 2008/84/EC and Regulation 1333/2008/EC. The product complies with FDA §182.1320 of the GRAS status (Generally Recognized as Safe).	
PHARMACOPOEIA	Complies with EP VII ed. (2011), USP-NF	

the final user being fully responsible for the adoption and the correct usage of the product.



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