

Farmalabor
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Farmacisti AssociatiFarmalabor
TECHPackaging for pharmaceutical
and cosmetic useRaw materials for pharmaceutical
cosmetic and food useEquipment and furniture
for galenic laboratory**CERTIFICATE OF ANALYSIS**Product **1202A Vegetable glycerol EP USP**Batch Number **R1201173 - 04051**

Manufacturer

Retest date

14/04/2013

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	Pharmaceutical and food use (E422)
APPEARANCE	Clear and colourless, syrupy liquid, very hygroscopic (20°C)
ODOUR	Complies
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.
APPLICATIONS	In topical pharmaceutical formulations and cosmetics, glycerin is used primarily 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.
RECOMMENDED DOSAGE	Antimicrobial preservative < 20%; Emollient <= 30%; Gel vehicle, aqueous 5-15%; Gel vehicle, nonaqueous: 50-80%; Humectant <= 30%

FARMADENT d.o.o.	
Minarikova ul. 6	
2000 Maribor	
Prejel: FARMADRAGO	
Datum programa:	27.2.2012
Pregledal:	MAROLT Robert mag. farm., spec.
Datum pregleda:	30.7.2011

ANALYSIS	LIMITS	RESULTS
ASSAY	Glycerol content >= 99,70% w/w Complies (USP)	99,88% Complies
IDENTITY	Identification A (Refractive index): conform Identification B (IR): conform Identification C (Nitric acid): conform Identification D (Acroleine test): conform Identification B (USP): conform Identification C (USP): conform	Conform Conform Conform Conform 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 mcg/g (USP)	< 5 ppm < 5 mcg/g
SULFATES	<= 0,002% w/w (USP)	< 0,002%
CHLORIDES	<= 10 ppm (EP) <= 10 ppm (EP)	< 0,001% < 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 batch release of active pharmaceutical ingredients in compliance with the Article 47 of Directive 2001/83/EC

The Company's Quality
is recognized by certification:
ISO 9001:2008
ISO 14:001:2004



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ANALYSIS	LIMITS	RESULTS
ACIDITY/ALCALINITY	Complies with EP Acidity (APAG) $\leq 0,08$ meq/100 g Alkalinity (EP) $\leq 0,00$ ml NaOH 0,1 M	Complies 0,02 meq/100 g 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 - impurity A (DEG) $\leq 0,1\%$ - any other impurity eluting before Glycerol: $\leq 0,1\%$ - total impurities eluting after Glycerol: $\leq 0,5\%$ DEG and related compounds (USP): conform - any individual impurity (excluding DEG) $\leq 0,1\%$ - total impurities, including DEG: $\leq 1,0\%$ - Diethylene glycol $\leq 0,025\%$ - Ethylene glycol $\leq 0,025\%$	Conform $< 0,1\%$ $< 0,1\%$ $< 0,5\%$ Conform $< 0,1\%$ $< 1,0\%$ $< 0,025\%$ $< 0,025\%$
ALDEHYDES	≤ 10 ppm (EP)	< 10 ppm
SUGARS	Conform (EP)	Conform
IMPURITIES	Chlorinated compounds (USP) $\leq 0,003\%$ w/w (USP) Halogenated compounds ≤ 30 ppm (EP)	$< 0,003\%$ < 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): the product is food approved according to EU Directive 2008/84/EC and Regulation 1333/2008/EC. The product complies with FDA §182.1320 on the GRAS status (Generally Recognized as Safe).

PHARMACOPOEIA Complies with EP VII ed. (2011), USP-NF

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
Giovanni Summonte

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