Farmalabor PACK — Packaging for pharmaceutical and cosmetic use

FARMALABO — Farmacisti Associati

Farmalabor TECH — Equipment and furniture for galenic laboratory

Raw materials for pharmaceutical cosmetic and food use

CERTIFICATE OF ANALYSIS

Product 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	Pharmaceutical and food use (E422)
APPEARANCE	Clear and colourless, syrupy liquid, very hygroscopic (20°C)
SOLUBILITY	Soluble in water, alcohol; slightly soluble in acetone
STORAGE	Store at room temperature, in a cool and aerated place.
PROPERTIES	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.
APPLICATIONS	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	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%.

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FU-JS-DRAGO
Zap.:
Datum prejema: 27.7.2012
Pregledal: MAG. LT Robert, mag. farm., spec.
Datum pregleda: 30.7.2012

ANALYSIS	LIMITS	RESULTS
ASSAY	Glycerol content >= 99,70% w/w	99,80%
IDENTITY	Conform (USP)	Complies
	Identification A (Refractive index): conform	Complies
	Identification B (IR): conform	Complies
	Identification C (Nitric acid): conform	Complies
	Identification D (Evaporating test): conform	Complies
	Identification B (USP): conform	Complies*
	Identification C (USP): conform	Complies*
COLOUR	APHA color: <= 10	5,0
ODOUR	Conform	Complies
DENSITY	>= 1,2490 g/ml at 25°C (USP)	1,2615 g/ml
APPEARANCE OF SOLUTION	Conform (EP)	Complies
REFRACTIVE INDEX	1,473-1,474 (20°C)	1,474

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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 *
	<= 5 mcg/g (USP)	< 5 mcg/g *
SULFATES	<= 0,002% w/w (USP)	< 0,002% *
CHLORIDES	<= 0,001% w/w (USP)	< 0,001%
	<= 10 ppm (EP)	< 10 ppm
ACIDITY/ALCALINITY	Alkalinity (EP) <= 0,00 ml NaOH 0,1 M	0,00 ml
	Acidity (EP): <= 0,20 ml NaOH 0,1 M	0,05 ml
	Conform (EP)	Complies
	Acidity (APAG) <= 0,08 meq/100 g	0,02 meq/100 g
FATTY ACIDS AND ESTERS	<= 1 ml 0,5N NaOH (USP)	< 1 ml
ESTERS	>= 8,0 ml HCl 0,1M (EP)	> 8,0 ml
RELATED SUBSTANCES	Impurity A and related substances: conform	Complies
	- 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	Complies
	- 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)	Complies
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	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 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

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

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