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Kirsch Pharma España
Grupo Kirsch Pharma GmbH S. L. Unipersonal

LOTE: VE6C200151

oleon
a natural chemistry

Oleon NV c/o Oleon SAS
Rue Les Rives de l'Oise
F-60280 Venette
FRANCE

Delivery Address
KIRSCH PHARMA
CL/ALONSO BARBA 7
28806 MADRID-PARQUE EMPRESARIAL LA GARENA
SPAIN

Certificate of Analysis

Loading date
26/03/2020

Ordernumber Oleon
85679338 900001 30486733 000010

Your reference / Date
BG-2020/8.462 /

Product Information
Description GLYCERINE 4810 99,5%
Glycerin 99.5% Ph.Eur./USP (E422)

Quantity 3,000 TO
Batch VE6C200151 **Sample** 2/618559/00 / **Production date** 29/01/2020 / **Expiration date** 29/01/2022

Results of analysis	Unit	Results		Min.	Max.	Method
Refractive Index at 20°C		1,474		1,473	1,475	Eur.Ph.
Glycerol Content	%(m/m)	99,81	>=	99,70		APAG-GL-009
Assay	%(m/m)	99,8		99,0	101,0	USP-NF
Assay	%(m/m)	99,8		98,0	101,0	Eur.Ph.
Relative Density @ 20°C/20°C		1,264		1,258	1,268	Eur.Ph.
Colour APHA		2,5	<=		10,0	ISO 2211
Acidity	meq/100g	0,02	<=		0,08	ISO 1615
Acidity / ml 0,1 M NaOH	ml	0,05	<=		0,20	Eur.Ph.
Alkalinity / ml 0,1 M HCl	ml	0,00	<=		0,00	Eur.Ph.
Acidity or Alkalinity (EP)		Conform		-	-	Eur.Ph.
Odour		Conform		-	-	Oleon GLY07
Water	%(m/m)	0,19	<=		0,30	Eur.Ph./USP-NF
Specific gravity at 25°C	g/ml	1,2622	>=	1,2490		USP-NF
Identification A (Refractive index)		Conform		-	-	Eur.Ph.
Identification B (Infrared)		Conform		-	-	Eur.Ph.
Appearance of solution		Conform		-	-	Eur.Ph.
Aldehydes	ppm(m)	< 10	<=		10	Eur.Ph.
Esters / 0,1 M HCl	ml	> 8,0	>=	8,0		Eur.Ph.
Imp. A and related substances (EP)		Conform		-	-	Eur.Ph.
-impurity A (DEG)	%	< 0,1	<=		0,1	Eur.Ph.
-any other impurity eluating before glyc	%	< 0,1	<=		0,1	Eur.Ph.
-total impurities eluating after glyc	%	< 0,5	<=		0,5	Eur.Ph.
Halogenated compounds	ppm(m)	< 30	<=		30	Eur.Ph.
Sugars		Conform		-	-	Eur.Ph.
Chlorides	ppm	< 10	<=		10	Eur.Ph.
Sulphated ash	%	< 0,01	<=		0,01	Eur.Ph.

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Results of analysis	Unit	Results			Min.	Max.	Method
Residual solvents, Methanol	ppm	< 300	h	<=		300	Eur.Ph./USP-NF
Identification B		Conform	h		-	-	USP-NF
Identification C		Conform	h		-	-	USP-NF
Residue on ignition	%(m/m)	< 0,01	h	<=		0,01	USP-NF
Chloride	%(m/m)	< 0,001	h	<=		0,001	USP-NF
Sulfate	%(m/m)	< 0,002	h	<=		0,002	USP-NF
Limit of Chlorinated compounds	%(m/m)	< 0,003	h	<=		0,003	USP-NF
Fatty acids & esters / 0.5 N NaOH	ml	< 1	h	<=		1	USP-NF
Limit of DEG and related compounds		Conform	h		-	-	USP-NF
-any individual impurity (excl. DEG)	%	< 0,1	h	<=		0,1	USP-NF
-total impurities including DEG	%	< 1,0	h	<=		1,0	USP-NF
-Diethylene glycol	%	< 0,025	h	<=		0,025	USP-NF
-Ethylene glycol	%	< 0,025	h	<=		0,025	USP-NF

This product complies with the component's monograph as described in the current edition of the European Pharmacopoeia (Ph. Eur.).
This product complies with the component's monograph as described in the current edition of the US Pharmacopoeia (USP-NF).
The product is manufactured from vegetable raw materials.
The product does not contain any ingredients that are derived from GM sources. However relevant thresholds for adventitious or technically unavoidable cross-contamination as laid down in 1829/2003/EC are accepted. Moreover, the above mentioned material has not to be labeled according to Regulation (EC)1830/2003/EC concerning traceability and labeling of food and feed products manufactured from genetically modified organisms.
The product is in compliance with the consensus guideline CPMP/ICH/283/95 last updated February 2011 Q3C(5) concerning the residual solvents edited by EMEA.
The product complies with the microbiological purity criteria of European Pharmacopoeia monographs EP 2.6.12 and EP 2.6.13.
The product is food approved according to EU Regulation 231/2012 and EC Regulation 1333/2008.
The product complies with FDA §182.1320 on the GRAS status (Generally Recognized As Safe).

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Oleon SAS
Stéphanie Ledoare
If you have any questions relating to this certificate of Analysis please revert to your sales contact person
This document is system generated and does not require a signature.

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