

Certificate of Analysis

Product name: **Glyceroli monostearas 40-55**

Batch number / Weight: **22A19-B06-218229 / 250 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22A19-B06 / INS-22-3599**

Reference Code / No.: **V01136 / 008120**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Hard, waxy mass or unctuous powder or flakes, white or almost white	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Acid value	$\leq 3,0$	1,67		
Iodine value	$\leq 3,0$	0,18		
Saponification value	158 - 177	170,0		
Free glycerol	$\leq 6,0$	0,67	%	
Composition of fatty acids (Type	Conform	Conform		
Assay Stearic acid	60,0 - 80,0	69,32	%m/m	
Assay Palmitic and stearic acid	$\geq 90,0$	97,52	%m/m	
Water	$\leq 1,0$	0,49	%	
Total ash	$\leq 0,1$	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Monoacylglycerols	40,0 - 55,0	46,5	%m/m	
Assay Diacylglycerols	30,0 - 45,0	42,2	%m/m	
Assay Triacylglycerols	5,0 - 15,0	9,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, ElSpol

Release:
Ewelina Gadzinowska
Qualified Person

07-10-2022

Expiration: 31-08-2023

Conclusion: APPROVED

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