

Certificate of Analysis

Product name: Levomentholum (syntheticum)

Batch number / Weight: 23J09-B04-231752 / 250 G

Analysed according to: Ph.Eur.11.2

Number of analysis / Inspection Code 23J09-B04 / INS-23-8140

Reference Code / No.: V01545 / 10300463

Tests	Requirement	Result	Unit	Standard remark
Appearance	colorless to white pellets	conform		
Identification A	-48 - -51	-49,7		
Identification C	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Acidity or alkalinity	Conform	Conform		
	<=0,5 ml NaOH (0,01M)	0,20	ml	
Specific optical rotation	-48 - -51	-49,7		
Related substances	<= 1	0,0	%	
Residue on evaporation	<= 0,05	0,015	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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 lab

Release:

Agnieszka Pszczółka

Qualified Person

30-11-2023

Expiration: 30-06-2025

Conclusion: APPROVED

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