

Certificate of Analysis

Product name: **Levomentholum (syntheticum)**

Batch number / Weight: **22A26-B10-222446 / 250 G**

Analysed according to: **Ph.Eur.10**

Number of analysis / Inspection Code **22A26-B10 / INS-22-3628**

Reference Code / No.: **V01545 / 10300378**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Prismatic or acicular, colourless, shiny crystals	Conform		
Identification A	-48 - -51	Conform		
Identification C	Conform	Conform		
Melting point	about 43	44,24	°C	
Appearance of solution	Clear and colourless	Conform		
Acidity or alkalinity	Conform	0,1ml NaOH		
Specific optical rotation	-48 - -51	-49,2		
Related substances	<=1	0,00	%	
Residue on evaporation	<= 0,05	0,005	%	
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
Residual solvents				
Methanol	<=3000	<3000	ppm	
Acetone	<5000 ppm	<5000	ppm	

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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 lab

Release:
Ewelina Gadzinowska
Qualified Person

12-09-2022

Expiration: 30-11-2023

Conclusion: APPROVED

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