

Certificate of Analysis

Product name: Phenolum cryst.
Batch number / Weight: 21J15-B05-213568 / 1 G
Analysed according to: Ph. Eur. 10
Number of analysis / Inspection Code 21J15-B05 / INS-22-1121
Reference Code / No.: V00621 / 93716

Tests	Requirement	Result	Unit	Standard remark
Appearance	Colourless or slightly pink to slightly yellow crystals with a characteristic odour	Conform		
Identification A	Deep blue	Conform		
Identification B	Violet / colourless	Conform		
Identification C	White precipitate	Conform		
Appearance of solution	Clear / $\leq B_6$	Conform		
Acidity	Conform	Conform		
Freezing point	$\geq 39,5$	41,00	°C	
Residue on evaporation	$\leq 0,05$	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Phenol	99,0 - 100,5	99,41	%m/m	
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

26-10-2022

Expiration: 30-09-2024

Conclusion: APPROVED

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