

Certificate of Analysis

Productname: Chlorobutanolum hemihydricum
Number of analysis/Inspection Code: 1 / KEUR-184453B
Batchnumber: 20C13-F03-370982
Reference code / No.: 3318 / 26002076
Analysed according to: PH.EUR10.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	4,5 - 5,5	Conform		Water
Appearance of solution	<=ref. susp. II <=BY5	Conform		50 m/V in alcohol
Acidity	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	< 60	<60	ppm	
Impurity B	<=0,10	<0,1	%	
Chlorides	<=100	Conform	ppm	
Water (Karl Fischer)	4,5 - 5,5	4,9	%	
Sulphated ash	<=0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Chlorobutanol	98,0 - 101,0	99,3	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

07/23/20

Expiration: 11-2024

Conclusion: APPROVED

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