

Certificate of Analysis

Productname: Gabapentinum
Number of analysis/Inspection Code: 1 / KEUR-180730B
Batchnumber: 19J03-F02-367027
Reference code / No.: 1250 / 3099/91357
Analysed according to: USP 42

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to off-white, crystalline solid	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		HPLC
pH	6,5 - 8,0	7,2		
Water (Karl Fischer)	<=0,5	0,0	%	
Related substances, early-eluting organic	Conform	Conform	%	
Impurity E	<=0,10	<0,01	%	
Impurity A	<=0,1	0,0	%	
Impurity B	<=0,06	<0,01	%	
Any other impurity	<=0,10	0,10	%	
Related substances, late-eluting organic	Conform	Conform		
Impurity D	<=0,10	<0,01	%	
Any other impurity	<=0,10	<0,01	%	
Total impurities	<=0,5	0,3	%	
Residue on ignition	<=0,1	<0,01		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Gabapentinum	98,0 - 102,0	98,4	%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:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/25/20

Expiration: 06-2024

Conclusion: APPROVED

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