

Certificate of Analysis

Productname: Omeprazolum
Number of analysis/Inspection Code: 1 / KEUR-180723B
Batchnumber: 19J29-F03-367825
Reference code / No.: 2445 / OPFP19017
Analysed according to: PH.EUR 9.8

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification	Conform	Conform		IR-spectrum
Appearance of solution	Clear	Conform		2% <i>m/V</i> MeCl
Impurity F and G	<=350	<350	ppm	E 440 nm
Related substances	Conform	Conform		HPLC
Impurity D	<=0,15	0,11	%	
Impurity E	<=0,15	0,00	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,1	%	
Loss on drying	<=0,2	0,1	%	4 h 60 °C; 670 Pa
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Omeprazole	99,0 - 101,0	100,1	% <i>m/m</i>	Dried
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

02/26/20

Expiration: 08-2024

Conclusion: APPROVED

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