

Certificate of Analysis

Productname: Omeprazolum
Number of analysis/Inspection Code: 1 / KEUR-198744B
Batchnumber: 21110-F02-385893
Reference code / No.: 2445 / OPFP21028
Analysed according to: PH.EUR10.5

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	0,10	%	
Impurity E	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,10	%	
Loss on drying	<=0,2	0,1	%	4 h 60 C; vacuum <0,1 kPa
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 Omeprazole	99,0 - 101,0	99,7	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Manufacturer / Country : Lee Pharma Limited (site) / IN
CEP :

Release:
Anthony Amoureux
Qualified Person

15-03-24

Expiration: 31-05-26

Conclusion: APPROVED

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