



Certificate of Analysis

OMEPRAZOLE MICRONIZED

Batch ID: OHMA1380
Manufacturing Date: Apr-2021

Product Description: OMEPRAZOLE MICRONIZED
Re-Test Date: Apr-2024

Product SAP Code: 102789

TEST	SPECIFICATION	RESULT
DESCRIPTION	White to off-white powder	Complies
IDENTIFICATION: IR ✓	Positive	Complies
COMPLETENESS OF SOLUTION (2%, methylene chloride) ✓	Clear solution	Complies
ABSORBANCE. LIMIT OF OMEPRAZOLE RELATED COMPOUNDS F&G (2% methylene chloride, absorbance at 440 nm) ✓	Not more than 0.10 AU *This limit corresponds to 350 ppm of the sum of impurities F and G.	0.04 AU
LOSS ON DRYING ✓	Not more than 0.2%	0.0 %
SULPHATED ASH ✓	Not more than 0.1%	0.02 %
TAPPED DENSITY	0.20 - 0.50 g/ml	0.25 g/mL
PARTICLE SIZE		
D (v,0.9)	Not more than 10 µm	8 µm
Mean diameter	Not more than 5 µm	4 µm
LOSS (0.1N NaOH) ✓	99.0 - 101.0% (on the dry substance)	100.0 %
RELATED SUBSTANCES (HPLC)		
Ph. Eur Impurity D ✓	Not more than 0.1%	<0.05 %
Ph. Eur. Impurity E ✓	Not more than 0.1%	<0.01 %
Any other single unspecified impurity ✓	Not more than 0.10%	<0.05 %
Total impurities ✓	Not more than 0.5%	<0.05 %
MONOETHANOLAMINE_CEP (HPLC)	Not more than 0.05 %	0.00 %

R1 CEP 1999-093 Rev 08



Dispositioned By: Francisco Fernandez (QA Release Manager)
Disposition Date: 05-05-2021

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Result: Approved