

# Certificate of Analysis

## OMEPRAZOLE MICRONIZED

**Batch ID:** OHMA0105  
**Manufacturing Date:** May-2020

**Product Description:** OMEPRAZOLE MICRONIZED  
**Re-Test Date:** May-2023

**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.	0.03 AU
LOSS ON DRYING	Not more than 0.2%	0.1 %
SULPHATED ASH	Not more than 0.1%	0.00 %
TAPPED DENSITY	0.20 - 0.50 g/ml	0.27 g/mL
PARTICLE SIZE		
D (v,0.9)	Not more than 10 µm	9 µm
Mean diameter	Not more than 5 µm	4 µm
LOSS (0.1N NaOH)	99.0 - 101.0% (on the dry substance)	99.0 %
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  
**Disposition Date:** Jun-2020

*This is an electronic signature*

**Result:** Approved