CHEMO

Certificate of Analysis

OMEPRAZOLE MICRONIZED

Batch ID: OHMA1599
Manufacturing Date: Dec-2021
Product Description: OMEPRAZOLE MICRONIZED
Re-Test Date: Dec-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.	0.05 AU
LOSS ON DRYING	Not more than 0.2%	0.0 %
SULPHATED ASH	Not more than 0.1%	0.08 %
TAPPED DENSITY	0.20 - 0.50 g/ml	0.29 g/mL
PARTICLE SIZE		
D (v,0.9)	Not more than 10 µm	10 µm
Mean diameter	Not more than 5 µm	4 µm
ASSAY (0.1N NaOH)	99.0 - 101.0% (on the dry substance)	99.2 %
RELATED SUBSTANCES (HPLC)		
Ph. Eur Impurity D	Not more than 0.1%	<0.01 %
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 %

Complies with Ph.Eur.R1CEP 1999-093 Rev 08.Manufactured in compliance with cGMP requirements.

METAPHARMACEUTICAL

N DE LOTE:
0 13 06 22

13 JUN. 2023

Nº lote ACOFARMA:
222634
Firma y fecha: 11/05/22

Dispositioned By: Francisco Fernandez (QA Release Manager)
Disposition Date: 24-01-2022

This is an electronic signature

Result: Approved

MANUFACTURING SITE:
Química Sintética S.A.
Calle de Dulcinea, s/n, 28805 Alcalá de Henares, Madrid - SPAIN
Tlf. +34 91 889 85 77

LIMS Spec ID: ZOPROL_H_MICRON.COMMON.12
CoA Setup: Final Product ENGLISH Int. Reference: 4
Report: 10382 Date: 18/04/2022 10:23 CEST Time From: Database: LW_INSUD_PROD