

**OMEPRAZOL POLVO (EUR. PH.)**

PRODUCT CODE: 151367		CAS Nº: 73590-58-6	ANALYSIS Nº: 310/24
MANUFACTURER BATCH:	OPZ-11324	CERTIFICATE ID:	44.391
SUPPLIER BATCH:	241815	MANUFACTURING DATE:	01/08/2024
METAPH BATCH:	0351124	EXPIRY DATE:	03/07/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder (*)
Solubility	Very slightly soluble in water, soluble in methylene chloride, sparingly soluble in ethanol (96 %) and in methanol. It dissolves in dilute solutions of alkali hydroxides	Complies
Identification	Complies	Complies (*)
Appearance of solution	Clear	Complies
Impurities F and G		
Sum of the contents	=< 350 ppm	< 350 ppm
Related substances		
Impurity D	=< 0.15 %	< 0.05 %
Impurity E	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	0.09 %
Total impurities	=< 0.5 %	0.09 %
Loss on drying	=< 0.2 %	0.04 % (*)
Sulfated ash	=< 0.1 %	0.06 % (*)
Assay	99.0 - 101.0 %	99.3 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Omeprazole is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the product in airtight containers, protected from light and at a temperature between 2-8 °C.

Analysis date: 11/12/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001528
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