



FUROSEMIDA (EUR. PH.)

PRODUCT CODE: 1031	CAS Nº: 54-31-9	ANALYSIS Nº: 330/24
MANUFACTURER BATCH: RF-0824052	CERTIFICATE ID: 44.578	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/08/2024	
METAPH BATCH: 0171224	EXPIRY DATE: 31/07/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 %), practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides	Complies (*)
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY5	Complies
Related substances		
Impurity C	=< 0.2 %	< 0.2 %
Impurity D	=< 0.15 %	< 0.15 %
Unspecified impurities	=< 0.10 %	< 0.10 %
Total impurities	=< 0.5	< 0.5 %
Chlorides	=< 200 ppm	< 200 ppm
Sulfates	=< 300 ppm	< 300 ppm
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	98.5 - 101.0 %	100.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the certificate of analysis of the manufacturer.

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

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

Analysis date: 27/05/2025

Signature: Cristina Borrell Olea (QA/QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40001200

SRI KRISHNA PHARMACEUTICALS LIMITED
UNIT IV

Survey No 296/7/10, IDA, Bollaram,
Jinnaram Mandal