

FUROSEMIDA (EUR. PH.)			
PRODUCT CODE: 1031		CAS Nº: 54-31-9	ANALYSIS Nº: 311/23
MANUFACTURER BATCH:	RF-0823546	CERTIFICATE ID:	40.587
SUPPLIER BATCH:	----	MANUFACTURING DATE:	31/08/2023
METAPH BATCH:	0191223	RETEST DATE:	31/07/2028

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 %	< 0.05 %
Impurity D	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5	< 0.05 %
Chlorides	=< 200 ppm	< 200 ppm
Sulfates	=< 300 ppm	< 300 ppm
Loss on drying	=< 0.5 %	0.1 %
Sulfated ash	=< 0.1 %	0.02 %
Assay	98.5 - 101.0 %	100.1 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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

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: 31/01/2024
 Signature: Albert Sánchez López (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

