METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1031-TDS-ENG-2023

FUROSEMIDA (EUR. PH.)		
DESCRIPTION DCI: FUROSEMIDE	DESCRIPTION DOE: FUROSEMIDA	
CAS Nº: 54-31-9	EC Nº: 200-203-6	AEMPS CODE: 1615A
MOL. WEIGHT: 330.74	MOL. FORMULA: C12H11ClN2O5S	ARTICLE CODE: 1031

ATTRIBUTES	SHOULD BE
Appearance	White or almost 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
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY5
Related substances	
Impurity C	=< 0.2 %
Impurity D	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5
Chlorides	=< 200 ppm
Sulfates	=< 300 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.