METAPHARMACEUTICAL

# TECHNICAL DATA SHEET

1031-TDS-ENG-2026

| 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 12.1

## 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.



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