



TECHNICAL DATA SHEET

219-TDS-ENG-2024

| BETAMETASONA SODIO FOSFATO (EUR. PH.) | | |
|---|--|---|
| DESCRIPTION DCI: SODIUM PHOSPHATE BETAMETHASONE | | DESCRIPTION DOE: BETAMETASONA FOSFATO SODIO |
| CAS Nº: 151-73-5 | EC Nº: 205-797-0 | AEMPS CODE: 491FN |
| MOL. WEIGHT: 516,4 | MOL. FORMULA: C ₂₂ H ₂₈ FN _a O ₈ P | ARTICLE CODE: 219 |

| ATTRIBUTES | SHOULD BE |
|---------------------------|---|
| Appearance | White or almost white, very hygroscopic powder. |
| Solubility | Freely soluble in water, slightly soluble in ethanol (96 %), practically insoluble in methylene chloride. |
| Identification A | Complies |
| Identification B | Complies |
| Appearance of solution | Clear and not more intensely colored than ref. sol. B7 |
| pH | 7.5 - 9.0 |
| Specific optical rotation | +98 / +104 |
| Related substances | |
| Any impurity | =< 2.0 % |
| Total impurities | =< 3.0 % |
| Fosfatos inorgánicos | =< 1.0 % |
| Water | =< 8.0 % |
| Assay | 96.0 - 103.0 % |

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

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

REMARKS

Betamethasone Sodium Phosphate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.