



TECHNICAL DATA SHEET

221-TDS-ENG-2024

BETAMETASONA ACETATO (EUR. PH.)		
DESCRIPTION DCI: BETAMETHASONE ACETATE		DESCRIPTION DOE: BETAMETASONA ACETATO
CAS Nº: 987-24-6	EC Nº: 213-578-6	AEMPS CODE: 491AC
MOL. WEIGHT: 434,50	MOL. FORMULA: C ₂₄ H ₃₁ FO ₆	ARTICLE CODE: 221

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder.
Solubility	Practically insoluble in water, freely soluble in acetone, soluble in ethanol (96 %) and in methylene chloride
Identification A	Complies
Identification B	Complies
Specific optical rotation	+120 / +128
Related substances	
Impurity A	=< 0.5 %
Impurity B	=< 0.5 %
Impurity C	=< 0.5 %
Impurity D	=< 0.5 %
Total impurities	=< 1.25 %
Water	=< 4.0 %
Assay	97.0 - 103.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

It shows polymorphism.

Betamethasone Acetate 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.