METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

001964-TDS-ENG-2023

DEXAMETASONA BASE (PH.EUR)		
DESCRIPTION DCI: DEXAMETHASONE	DESCRIPTION DOE: DEXAMETASONA	
CAS Nº: 50-02-2	EC Nº: 200-003-9	AEMPS CODE: 722A
MOL. WEIGHT: 392.46	MOL. FORMULA: C22H29FO5	ARTICLE CODE: 001964

ATTRIBUTES	SHOULD BE
Appearance	white or almost white, crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in anhydrous ethanol, slightly soluble in methylene chloride
Identification B	Complies
Identification C	Complies
Specific optical rotation	+86 / +92
Related substances	
Impurity G	=< 0.3 %
Impurity B	=< 0.15 %
Impurity F	=< 0.15 %
Impurity J	=< 0.15 %
Impurity K	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Assay	97.0 - 103.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Dexametasone 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.