



DEXAMETASONA BASE (EUR. PH.)

PRODUCT CODE: 001964	CAS Nº: 50-02-2	ANALYSIS Nº: 146/23
MANUFACTURER BATCH: NUD221202	CERTIFICATE ID: 38.444	
SUPPLIER BATCH: BT23004	MANUFACTURING DATE: 02/12/2022	
METAPH BATCH: 0300523	RETEST DATE: 02/12/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	white or almost white, crystalline powder	White crystalline powder (*)
Solubility	Practically insoluble in water, sparingly soluble in anhydrous ethanol, slightly soluble in methylene chloride	Complies
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Specific optical rotation	+86 / +92	+88
Related substances		
Impurity G	=< 0.3 %	0.10 %
Impurity B	=< 0.15 %	< 0.05 %
Impurity F	=< 0.15 %	< 0.05 %
Impurity J	=< 0.15 %	< 0.05 %
Impurity K	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	0.10 %
Loss on drying	=< 0.5 %	0.02 % (*)
Assay	97.0 - 103.0 %	98.5 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed inside the EU.

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.

(*) Data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

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

Analysis date: 25/05/2023
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000442
 TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.
 NO.19, XINYE 9th Street
 300462 West Area of Tianjin Economic-
 Techonological Development Area