METAPHARMACEUTICAL IND SL
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DEXAMETASONA BASE (EUR. PH.)

PRODUCT CODE: 001964	CAS Nº: 50-02-2	ANALYSIS Nº: 126/23	
MANUFACTURER BATCH:	DMS20221210	CERTIFICATE ID:	38.298
SUPPLIER BATCH:	----	MANUFACTURING DATE:	30/12/2022
METAPH BATCH:	0120523	EXPIRY DATE:	29/12/2027

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	+87
Related substances		
Impurity G	=< 0.3 %	< 0.05 %
Impurity B	=< 0.15 %	< 0.05 %
Impurity F	=< 0.15 %	< 0.05 %
Impurity J	=< 0.15 %	< 0.05 %
Impurity K	=< 0.15 %	Not detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.08 %
Assay	97.0 - 103.0 %	101.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

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.

(*) Data adapted from the certificate of analysis of the manufacturer.

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: 40000349
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