

DEXAMETASONA BASE (EUR. PH.)			
PRODUCT CODE: 001964		CAS Nº: 50-02-2	ANALYSIS Nº: 297/25
MANUFACTURER BATCH:	DXMFE25002	CERTIFICATE ID:	48.337
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/08/2025
METAPH BATCH:	0280925	RETEST DATE:	30/07/2030

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	+89.1
Related substances		
Impurity G	=< 0.3 %	< 0.05 %
Impurity B	=< 0.15 %	Not Detected
Impurity F	=< 0.15 %	Not Detected
Impurity J	=< 0.15 %	< 0.05 %
Impurity K	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.04 %
Assay	97.0 - 103.0 %	99.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Dexametasone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

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

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.

Release date: 26/11/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies



Manufacturer: 40001541
MAHARSHI PHARMA CHEM PRIVATE LIMITED
Block No.203, Vaso-Alindra Road, Po.Alindra, District Kheda, GUJARAT
387510
(India)

Original certificate available upon request

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STORAGE

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

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