METAPHARMACEUTICAL IND SL
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BETAMETASONA DIPROPIONATO (EUR. PH.)

PRODUCT CODE: 0238	CAS Nº: 5593-20-4	ANALYSIS Nº: 153/25	
MANUFACTURER BATCH:	BDP/M/011/25	CERTIFICATE ID:	46.710
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/03/2025
METAPH BATCH:	0400525	EXPIRY DATE:	28/02/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone and in methylene chloride, sparingly soluble in ethanol (96 per cent)	Conforme (*)
Identification A	Complies	Complies
Specific optical rotation	+84 / +88	+85.2
Related substances		
Impurity C	=< 0.5 %	0.5 %
Impurity B	=< 0.3 %	0.1 %
Impurity H	=< 0.3 %	< 0.05 %
Impurity D	=< 0.2 %	< 0.05 %
Impurity E	=< 0.2 %	< 0.05 %
Impurity G	=< 0.2 %	< 0.05 %
Impurity I	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	0.6 %
Loss on drying	=< 1.0 %	0.02 %
Assay	97.0 - 102.0 %	101.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

Betamethasone Dipropionate 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.

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

Analysis date: 25/09/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000620
AVIK PHARMACEUTICAL LTD.
A-1/7 & A-1/8, PHASE-1, GIDC
396195 VAPI
(Índia)