

BETAMETASONA VALERATO (EUR. PH.)

PRODUCT CODE: 0239	CAS Nº: 2152-44-5	ANALYSIS Nº: 094/21
MANUFACTURER BATCH: BV 111/0920	CERTIFICATE ID: 31.488	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/09/2020	
METAPH BATCH: 0170421	RETEST DATE: 30/08/2025	

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, soluble in ethanol (96 %)	Complies
Melting point	about 192 °C, with decomposition	195 °C
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+77 / +83	+79
Related substances		
Impurity A	=< 0.7 %	< 0.05 %
Impurity E	=< 0.3 %	< 0.05 %
Impurity G	=< 0.3 %	< 0.05 %
Impurity C	=< 0.15 %	< 0.05 %
Impurity H	=< 0.15 %	< 0.05 %
Impurity I	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.03 %
Assay	97.0 - 103.0 %	97.2 %
Residual solvents		(*) (**)
Methanol	=< 3000 ppm	< 3000 ppm
Acetone	=< 5000 ppm	< 5000 ppm
Methylene chloride	=< 600 ppm	< 600 ppm
Ethyl acetate	=< 5000 ppm	< 5000 ppm
Particle size	90 % (= < 20 µm)	90 % - 6.19 µm (*)

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Betamethasone Valerate is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

Analysis date: 10/05/2021
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000314
 SYMBIOTICA Speciality Ingredients Sdn. Bhd.
 No. 518, Jalan Waja, 4
 Taman Industri Waja
 09000 Kulim Kedah Darul Aman





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SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/09/2020
METAPH BATCH:	0170421	RETEST DATE:	30/08/2025

STORAGE

Keep only in the original container in a cool, dry and well-ventilated place.

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