

BETAMETASONA VALERATO (EUR. PH.)

PRODUCT CODE: 0239	CAS Nº: 2152-44-5	ANALYSIS Nº: 250/23
MANUFACTURER BATCH: BV 105/0423	CERTIFICATE ID: 39.759	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/04/2023	
METAPH BATCH: 0071023	RETEST DATE: 30/03/2028	

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	192 °C (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+77 / +83	+79.1
Related substances		
Impurity A	=< 0.7 %	< 0.05 %
Impurity E	=< 0.3 %	Not Detected
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 %	0.2 %
Assay	97.0 - 103.0 %	100.9 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Betamethasone Valerate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

(*) 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 only in the original container in a cool, dry and well-ventilated place.

Analysis date: 02/11/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000314
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 Taman Industri Waja
 09000 Kulim Kedah Darul Aman

