



BETAMETASONA VALERATO (EUR. PH.)					
PRODUCT CODE: 0239	CAS Nº: 2152-44	-5 ANAI	NALYSIS Nº: 094/21		
MANUFACTURER BATCH:	BV 111/0920	CERTIFICATE ID:	31.488		
SUPPLIER BATCH:		MANUFACTURING DATE:	01/09/2020		
МЕТАРН ВАТСН:	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	Complies	
	acetone and in methylene chloride, soluble in		
	ethanol (96 %)		
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

Page 1 of 2 A073.03.ENG





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STORAGE

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

Analysis date: 10/05/2021

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

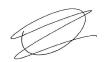
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Page 2 of 2 A073.03.ENG