



BETAMETASONA VALERATO (EUR. PH.)					
PRODUCT CODE: 0239	CAS Nº: 2152-44	-5 ANAI	ALYSIS Nº: 194/22		
MANUFACTURER BATCH:	BV 105/0322	CERTIFICATE ID:	35.794		
SUPPLIER BATCH:		MANUFACTURING DATE:	01/03/2022		
МЕТАРН ВАТСН:	0050922	RETEST DATE:	28/02/2027		

ATTRIBUTES	SHOULD BE	IS	
Appearance Solubility	White or almost white, crystalline powder Practically insoluble in water, freely soluble in	White crystalline powder Complies (*)	
Solubliney	acetone and in methylene chloride, soluble in ethanol (96 %)	Compiles ()	
Melting point	about 192 °C, with decomposition	194 °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 %	0.07 %	
Impurity I	=< 0.15 %	< 0.05 %	
Unspecified impurities	=< 0.10 %	< 0.05 %	
Total impurities	=< 1.5 %	0.07 %	
Loss on drying	=< 0.5 %	0.02 %	
Assay	97.0 - 103.0 %	101.3 %	
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)	5.14 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: 20/10/2022

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

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STORAGE

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

Analysis date: 20/10/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

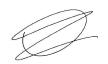
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