

BETAMETASONA DIPROPIONATO (EUR. PH.)

PRODUCT CODE: 0238	CAS Nº: 5593-20-4	ANALYSIS Nº: 202/22
MANUFACTURER BATCH: BDP 102/0422	CERTIFICATE ID: 35.898	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/04/2022	
METAPH BATCH: 0150922	RETEST DATE: 30/03/2027	

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)	Complies
Identification A	Complies	Complies
Specific optical rotation	+84 / +88	+84.1
Related substances		
Impurity C	=< 0.5 %	0.34 %
Impurity B	=< 0.3 %	0.05 %
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 %	0.39 %
Loss on drying	=< 1.0 %	0.10 %
Assay	97.0 - 102.0 %	100.5 %
Residual solvents [In-house]		(*) (**)
Methanol	=< 3000 ppm	Complies
Methylene chloride	=< 600 ppm	Complies
Pyridine	=< 200 ppm	Complies
Particle size	100 % =< 20 µm	Complies

COMPLIES WITH

European Pharmacopoeia 10.3

REMARKS

Betamethasone Dipropionate 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.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

(*) Data adapted from the manufacturer's certificate of analysis.

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

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: 30/09/2022
 Signature: Cristina Borrell Olea (QA/QP)
 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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STORAGE

Keep the container tightly closed. Store it in a dry and cool place.

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