

BETAMETASONA DIPROPIONATO (EUR. PH.)

PRODUCT CODE: 0238	CAS Nº: 5593-20-4	ANALYSIS Nº: 038/23
MANUFACTURER BATCH: APL/BDP/01253/K-22	CERTIFICATE ID: 37.311	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/11/2022	
METAPH BATCH: 0130223	EXPIRY DATE: 30/10/2027	

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
Related substances		
Impurity C	=< 0.5 %	0.37 %
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 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	0.37 %
Loss on drying	=< 1.0 %	0.08 %
Assay	97.0 - 102.0 %	98.6 %
Residual solvents [In-house]		(*) (**)
Methanol	=< 3000 ppm	Not Detected
Methylene chloride	=< 600 ppm	345.58 ppm
Pyridine	=< 200 ppm	Not Detected
Acetone	=< 5000 ppm	192.51 ppm
Dimethylformamide	=< 880 ppm	Not Detected
Ethyl acetate	=< 5000 ppm	Not Detected
Particle size		(*)
=< 20 µm	100 %	Complies

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

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 manufacturer's certificate of analysis.

(**) 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

Analysis date: 23/03/2023
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000473
 ANUH PHARMA Ltd.
 3-A Shivsagar Estate, North Wing
 Dr Annie Besant Road Worli
 400018 Maharashtra





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product before use.

STORAGE

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

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