METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

0222-TDS-ENG-2021

BECLOMETASONA 17,21 DIPROPIONATO		
DESCRIPTION DCI: BECLOMETASONE DIPROPIONATE	DESCRIPTION DOE: BECLOMETASONA DIPROPIONATO	
CAS Nº: 5534-09-8	EC Nº: 226-886-0	AEMPS CODE: 463DE
MOL. WEIGHT: 521.05	MOL. FORMULA: C28H37CIO7	ARTICLE CODE: 0222

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Identification C	Complies
Specific optical rotation	+108 / +115
Related substances	
Impurity L	=< 0.6 %
Impurity B	=< 0.5 %
Impurity F	=< 0.5 %
Impurity M	=< 0.5 %
Impurity A	=< 0.2 %
Impurity D	=< 0.2 %
Impurity N	=< 0.2 %
Impurity C	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.5 %
Loss on drying	=< 0.5 %
Assay	96.0 - 102.0 %
Residual solvents	
Methanol	=< 3000 ppm
Acetone	=< 5000 ppm
Isopropyl alcohol	=< 5000 ppm
Methylene chloride	=< 600 ppm
Dimethylformamide	=< 880 ppm
Particle size	
D (10 %)	< 2 µm
D (50 %)	< 5 µm
D (90 %)	< 10 µm
Microbiological control	
TAMC	< 1000 CFU/g
TYMC	< 100 CFU/g
Escherichia coli	Absence/1g
Pseudomonas aeruginosa	Absence/1g
Staphylococcus aureus	Absence/1g
Candida Albicans	Absence/1g

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ATTRIBUTES	SHOULD BE
Enterobacter aerogenes	Absence/1g
Clostridia sporogenes	Absence/1g
Salmonella	Absence/10g

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Keep the container tightly closed in a fresh and dry place.

REMARKS

Beclometasone Dipropionate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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.