METAPHARMACEUTICAL IND SL
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BUDESONIDA (EUR. PH.)

PRODUCT CODE: 010971	CAS Nº: 51333-22-3	ANALYSIS Nº: 228/22	
MANUFACTURER BATCH:	NB2836M	CERTIFICATE ID:	36.284
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/10/2021
METAPH BATCH:	0111022	EXPIRY DATE:	30/10/2026

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Related substances		
Impurity A	=< 0.2 %	0.10 %
Impurity L	=< 0.2 %	0.06 %
Impurity D	=< 0.2 %	0.07 %
Impurity K	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	0.06 % (Impurities G)
Total impurities	=< 0.5 %	0.29 %
Epimer A	40.0 - 51.0 %	48.4 %
Loss on drying	=< 0.5 %	0.03 %
Assay	97.5 - 102.0 %	97.9 %
Residual solvents		(*) (**)
Acetone	=< 5000 ppm	< LoQ
Methanol	=< 1000 ppm	67 ppm
Isopropyl ether	=< 500 ppm	< LoD
Tetrahydrofuran	=< 360 ppm	< LoD
Pyridine	=< 200 ppm	< LoD
Butiric aldehyde	=< 170 ppm	< LoQ
Particle size		(*)
=< 10 µm	100 %	100 %
=< 5 µm	=> 99.5 %	100 %
Microbiological control		(*)
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence	Absence
Salmonella	Absence	Absence
Pseudomonas aeruginosa	Absence	Absence
Staphylococcus aureus	Absence	Absence
Clostridium sporogenes	Absence	Absence
Candida Albicans	Absence	Absence
Gram negative bacteria	Absence	Absence

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Budesonide is subjected to the requirements of the ICH Q3D "Elemental Impurities".

Analysis date: 30/11/2022
Signature: Ferran Gonzalez de Rivera Rier
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000294
NEWCHEM spa
Via Roveggia, 47
37136 Verona
Verona(Itàlia)

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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.

STORAGE

Keep the container tightly closed in a dry, cool and well-ventilated place.

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