



BUDESONIDA (EUR. PH.)

PRODUCT CODE: 010971	CAS Nº: 51333-22-3	ANALYSIS Nº: 221/21
MANUFACTURER BATCH: NB1509M	CERTIFICATE ID: 32.569	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/05/2021	
METAPH BATCH: 0080921	EXPIRY DATE: 30/05/2026	

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 %	0.12 %
Impurity L	=< 0.2 %	< 0.05 %
Impurity D	=< 0.2 %	< 0.05 %
Impurity K	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	0.12 %
Epimer A	40.0 - 51.0 %	47.7 %
Loss on drying	=< 0.5 %	0.06 % (*)
Assay	97.5 - 102.0 %	100.8 % (*)
Residual solvents		(**)
Acetone	=< 5000 ppm	Not Detected
Methanol	=< 1000 ppm	31 ppm
Isopropyl ether	=< 500 ppm	Not Detected
Tetrahydrofuran	=< 360 ppm	Not Detected
Pyridine	=< 200 ppm	Not Detected
Butiric aldehyde	=< 170 ppm	Not Detected
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

Product fully analyzed inside the EU.

Analysis date: 17/09/2021

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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Budesonide 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 controlled by Metapharmaceutical Industrial SL.

(**) 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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