



## BUDESONIDA (EUR. PH.)

PRODUCT CODE: 010971	CAS Nº: 51333-22-3	ANALYSIS Nº: 176/20
MANUFACTURER BATCH: NA1554M	CERTIFICATE ID: 29.319	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 30/05/2020	
METAPH BATCH: 0150720	EXPIRY DATE: 30/05/2025	

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 %	46.5 %
Loss on drying	=< 0.5 %	0.19 %
Assay	97.5 - 102.0 %	98.4 %
Residual solvents		(*) (**)
Acetone	=< 5000 ppm	< LoD
Methanol	=< 1000 ppm	47 ppm
Isopropyl ether	=< 500 ppm	< LoD
Tetrahydrofuran	=< 360 ppm	< LoD
Pyridine	=< 200 ppm	< LoD
Butiric aldehyde	=< 170 ppm	< LoQ
Particle size		(*)
=< 10 µm	100 %	100.00 %
=< 5 µm	=> 99.5 %	99.98 %
Microbiological control		(*)
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence	Absence
Salmonella	Absence	Absence

### COMPLIES WITH

European Pharmacopoeia 10.0

### REMARKS

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 adapted from the certificate of analysis of the manufacturer.

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

Analysis date: 29/10/2020

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000294

NEWCHEM spa

Via Roveggia, 47

37136 Verona

Verona(Itàlia)



<b>BUDESONIDA (EUR. PH.)</b>			
PRODUCT CODE: 010971		CAS Nº: 51333-22-3	ANALYSIS Nº: 176/20
MANUFACTURER BATCH:	NA1554M	CERTIFICATE ID:	29.319
SUPPLIER BATCH:	----	MANUFACTURING DATE:	30/05/2020
METAPH BATCH:	0150720	EXPIRY DATE:	30/05/2025

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.

Analysis date: 29/10/2020  
Signature: Ferran Gonzalez de Rivera Rier  
Conclusion: Complies  
Original certificate available upon request

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