METAPHARMACEUTICAL

TECHNICAL DATA SHEET

010971-TDS-ENG-2026

BUDESONIDA (EUR. PH.)		
DESCRIPTION DCI: BUDESONIDE	DESCRIPTION DOE: BUDESONIDA	
CAS Nº: 51333-22-3	EC Nº: 257-139-7	AEMPS CODE: 2291A
MOL. WEIGHT: 430.53	MOL. FORMULA: C25H34O6	ARTICLE CODE: 010971

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, sparingly soluble in ethanol (96 %)
Identification A	Complies
Related substances	
Impurity A	=< 0.2 %
Impurity L	=< 0.2 %
Impurity D	=< 0.2 %
Impurity K	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Epimer A	40.0 - 51.0 %
Loss on drying	=< 0.5 %
Assay	97.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

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

REMARKS

BUDESONIDE is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.

Metapharmaceutical Industrial S.L.U. Josep Plà, 163 2º 5ª - 08020 BARCELONA - SPAIN - telf. 93 308 99 76 e-mail: info@metaph.es - www.metaph.es
Registro Mercantil de Barcelona, Tomo 9801, Libro 8942 de la sección 2ª, folio 179, hoja 112.120, inscripción 3ª - CIF. B-58736869