METAPHARMACEUTICAL IND SL
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# BUDESONIDE (EUR. PH.)

| | | | |
|---|---|---|---|
| PRODUCT CODE: 010971 | CAS Nº: 51333-22-3 | ANALYSIS Nº: 177/24 | |
| MANUFACTURER BATCH: | NE1089M | CERTIFICATE ID: | 42.787 |
| SUPPLIER BATCH: | ---- | MANUFACTURING DATE: | 01/04/2024 |
| METAPH BATCH: | 0230624 | EXPIRY DATE: | 30/04/2029 |

| 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 % | Not Detected |
| Impurity L | =< 0.2 % | Not Detected |
| Impurity D | =< 0.2 % | Not Detected |
| Impurity K | =< 0.2 % | Not Detected |
| Unspecified impurities | =< 0.10 % | Not Detected |
| Total impurities | =< 0.5 % | Not Detected |
| Epimer A | 40.0 - 51.0 % | 46.8 % |
| Loss on drying | =< 0.5 % | 0.1 % |
| Assay | 97.5 - 102.0 % | 98.8 % |

## COMPLIES WITH

European Pharmacopoeia 11.0

## 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".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

## STORAGE

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

Analysis date: 02/08/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000294
NEWCHEM spa
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37136 Verona
Verona(Itàlia)