



TECHNICAL DATA SHEET

0409-TDS-ENG-2023

| CLOBETASOL 17 PROPIONATO (PH.EUR) | | |
|--|---|--|
| DESCRIPTION DCI: CLOBETASOL PROPIONATE | | DESCRIPTION DOE: CLOBETASOL PROPIONATO |
| CAS N°: 25122-46-7 | EC N°: 246-634-3 | AEMPS CODE: 618PR |
| MOL. WEIGHT: 466.98 | MOL. FORMULA: C ₂₅ H ₃₂ ClFO ₅ | ARTICLE CODE: 0409 |

| ATTRIBUTES | SHOULD BE |
|---------------------------|--|
| Appearance | White or almost white, crystalline powder |
| Solubility | Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96 %) |
| Identification | Complies |
| Specific optical rotation | +112 / +118 |
| Related substances | |
| Impurity B | =< 0.3 % |
| Impurity E | =< 0.3 % |
| Impurity A | =< 0.2 % |
| Impurity D | =< 0.2 % |
| Unspecified impurities | =< 0.10 % |
| Total impurities | =< 1.0 % |
| Loss on drying | =< 0.5 % |
| Sulfated ash | =< 0.1% |
| Assay | 97.0 - 102.0 % |

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed and in a dry and cool place.

REMARKS

Clobetasol Propionate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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.