CLOBETASOL 17 PROPIONATO (EUR. PH.)

PRODUCT CODE: 0409	CAS Nº: 25122-46-7	ANALYSIS Nº: 299/23
MANUFACTURER BATCH: CLO 006/0823	CERTIFICATE ID:	40.439
SUPPLIER BATCH: ----	MANUFACTURING DATE:	01/08/2023
METAPH BATCH: 0071223	RETEST DATE:	30/07/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone, sparingly soluble in ethanol (96 %)	Complies (*)
Identification	Complies	Complies
Specific optical rotation	+112 / +118	+115
Related substances		
Impurity B	=< 0.3 %	0.06 %
Impurity E	=< 0.3 %	Not Detected
Impurity A	=< 0.2 %	0.07 %
Impurity D	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	0.13 %
Loss on drying	=< 0.5 %	0.16 %
Sulfated ash	=< 0.1%	0.05 %
Assay	97.0 - 102.0 %	99.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

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.

(*) 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 tightly closed and in a dry and cool place.

Analysis date: 16/01/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000314
SYMBIOTICA Speciality Ingredients Sdn. Bhd.
No. 518, Jalan Waja, 4
Taman Industri Waja
09000 Kulim Kedah Darul Aman

Page 1 of 1

A073.03.ENG