



TECHNICAL DATA SHEET

151378-TDS-ENG-2024

DIHYDROTACHYSTEROL (EUR. PH.)		
DESCRIPTION DCI: dihydrotachysterol		DESCRIPTION DOE: DIHIDROTAQUISTEROL
CAS Nº: 67-96-9	EC Nº: 200-672-7	AEMPS CODE: 1767A
MOL. WEIGHT: 398,66	MOL. FORMULA: C ₂₈ H ₄₆ O	ARTICLE CODE: 151378

ATTRIBUTES	SHOULD BE
Appearance	Colourless crystals or white or almost white, crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone and in hexane, sparingly soluble in ethanol (96 %)
Identification	Complies
Specific optical rotation	+ 99 / + 103
Related substances	
Impurity A	=< 0,5 %
Impurity B	=< 0,5 %
Impurity C	=< 0,5 %
Any other impurity	=< 0,1 %
Total impurities	=< 1,0 %
Water	=< 0,1 %
Assay	97,0 - 102,0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store under an inert gas, in an airtight container, at a temperature of 2 - 8 °C.

REMARKS

It shows polymorphism.

Dihydrotachysterol 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.