

DIHYDROTACHYSTEROL (EUR. PH.)

PRODUCT CODE: 151378	CAS Nº: 67-96-9	ANALYSIS Nº: 178/24
MANUFACTURER BATCH: DHT20240301	CERTIFICATE ID: 42.790	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 10/03/2024	
METAPH BATCH: 0010724	EXPIRY DATE: 09/03/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless crystals or white or almost white, crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone and in hexane, sparingly soluble in ethanol (96 %)	Complies (*)
Identification	Complies	Complies
Specific optical rotation	+ 99 / + 103	+100
Related substances		
Impurity A	=< 0.5 %	0.2 %
Impurity B	=< 0.5 %	0.05 %
Impurity C	=< 0.5 %	0.2 %
Any other impurity	=< 0.1 %	Not Detected
Total impurities	=< 1.0 %	0.4 %
Water	=< 0.1 %	< 0.01 %
Assay	97.0 - 102.0 %	100.7 %

COMPLIES WITH

European Pharmacopoeia 11.0

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".

(*) 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

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

Analysis date: 29/07/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000349

