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Product Specifications

PhytoChol® Puriss (animal-origin free, vegetal-derived Cholesterol)

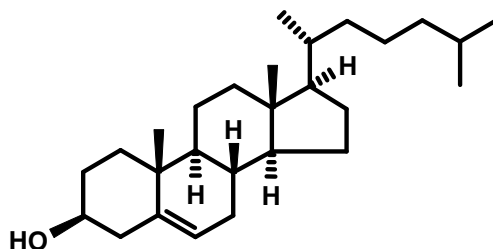
CAS 57-88-5

EINECS 200-353-2

Syn: Cholesterol; 3 β -Cholest-5-en-3-ol

Grade: Parenteral use

Structure:



Mol. Formula

C₂₇H₄₆O

Mol. Wt.

386.66

Source

Vegetal-derived, semi-synthetic

Retest Date

3 years

Conforms to the specifications of the monograph 2397 "Cholesterol for parenteral use", European Pharmacopoeia and the specifications for "Cholesterol", USP/NF

<i>Test</i>	<i>Specification</i>	<i>Results</i>
Appearance	White or almost white microcryst. powder	
Solubility	Practically insoluble in water; sparingly soluble in acetone and in ethanol (95%)	
Solubility (EtOH) (EP <2397>)	Clear solution	
Mp (Ph. Eur. 2.2.14)	147-150 °C	
Identification by GC (cf. Assay)	Conforms	
Color Test (Ph. Eur. test C)	Conforms	
Assay (GC, Ph. Eur. 2.2.28)	99.0-101.0%	
Other Sterols (GC, PH. Eur. 2.2.28)	≤ 0.5%	

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<i>Test</i>	<i>Specification</i>	<i>Results</i>
Benzoyl Ureas (HPLC, Ph. Eur. 2.2.29)		
• Impurity A (Diflubenzuron)	≤ 0.05 ppm	
• Impurity B (Triflumuron)	≤ 0.05 ppm	
LOD (Ph. Eur. 2.2.32)	≤ 0.1%	
Sulfated Ash (Ph. Eur. 2.4.14)	≤ 0.1%	
Residual Solvents (Ph. Eur. 5.4; USP <467>)		
• Methanol	≤ 3,000 ppm	
Acidity	≤ 0.1 mL of 0.1 M HCl	
Peroxide value (Ph. Eur. 2.5.5, Method A)	≤ 10	
Heavy Metals (Ph. Eur. 2.4.8)	≤ 10 ppm	
<u>Microbiological Specifications</u>		
Total Aerobic (CFU/g) (Ph. Eur. 2.6.12)	≤ 100 CFU/g	
Endotoxin Level (Ph. Eur. 2.6.14)	≤ 0.1 IU/mg	

Storage: Maintain in 15-30°C containment, protect from light.

Non-GMO: This product is derived from a non-GMO vegetal source as designated under EP regulations 1829/2003 and 1830/2003.

TSE/BSE: PhytoChol[®] is derived from a vegetal source. During production, storage and transport, all contact with any material of animal origin was excluded. Therefore, the requirements set forth in *Ph. Eur. 5.2.8*, do not apply.

US FDA DMF No.: 29599