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## Product Specifications

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

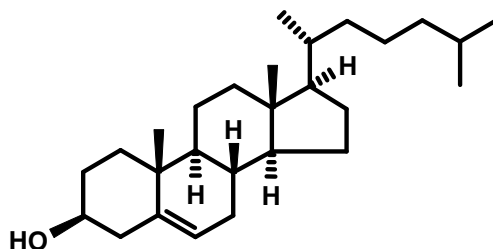
CAS 57-88-5

EINECS 200-353-2

Syn: Cholesterol; 3 $\beta$ -Cholest-5-en-3-ol

Grade: Parenteral use

Structure:



Mol. Formula

C<sub>27</sub>H<sub>46</sub>O

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>
<b>Appearance</b>	White or almost white microcryst. powder	
<b>Solubility</b>	Practically insoluble in water; sparingly soluble in acetone and in ethanol (95%)	
<b>Solubility</b> (EtOH) (EP <2397>)	Clear solution	
<b>Mp</b> (Ph. Eur. 2.2.14; USP <741>)	147-150 °C	
<b>Identification by GC</b> ( <i>cf.</i> Assay)	Conforms	
<b>Color Test</b> (Ph. Eur. test C; USP test B)	Conforms	
<b>Color Test</b> (USP test A)	Conforms	
<b>Assay</b> (GC, Ph. Eur. 2.2.28)	99.0-101.0%	
<b>Other Sterols</b> (GC, PH. Eur. 2.2.28)	≤ 0.5%	

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**Wilshire Technologies**

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<i>Test</i>	<i>Specification</i>	<i>Results</i>
<b>Benzoyl Ureas</b> (HPLC, Ph. Eur. 2.2.29)		
• Impurity A (Diflubenzuron)	≤ 0.05 ppm	
• Impurity B (Triflumuron)	≤ 0.05 ppm	
<b>LOD</b> (Ph. Eur. 2.2.32)	≤ 0.1%	
<b>Sulfated Ash</b> (Ph. Eur. 2.4.14)	≤ 0.1%	
<b>Residual Solvents</b> (Ph. Eur. 5.4; USP <467>)		
• Methanol	≤ 3,000 ppm	
<b>Acidity</b>	≤ 0.1 mL of 0.1 M HCl	
<b>Peroxide value</b> (Ph. Eur. 2.5.5, Method A)	≤ 10	
<b>Solubility</b> (EtOH) (EP <2397>)	Clear solution	
<b>Heavy Metals</b> (Ph. Eur. 2.4.8)	≤ 10 ppm	
<b><u>Microbiological Specifications</u></b>		
<b>Total Aerobic (CFU/g)</b> (Ph. Eur. 2.6.12)	≤ 100 CFU/g	
<b>Endotoxin Level</b> (Ph. Eur. 2.6.14)	≤ 0.1 IU/mg	

*Storage:* Maintain in 4°C containment.

*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**