

Product Specification	FINAL	Effective from	01.11.2015
Vitamin A-Palmitate 1.0 Mio IU/G stabilized with Tocopherol		PRD-No.	30041043
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NOT FOR REGULATORY PURPOSES

Test parameter	Requirement	Test method
Assay		
Vitamin A (photometr.)	1.00 to 1.10 million I.U./g	Ph. Eur.
Characters		
Appearance	Yellow viscous oil, partly crystalline when cooled	Visual
Identification		
Identity Vitamin A-Palmitate (TLC)	Must conform	PM00334
Test		
Peroxide value	≤ 10 meq/kg	Ph. Eur.
Acid value	≤ 2.0 mg KOH/g	Ph. Eur.
Retinol	≤ 1.0 g/100g	PM01096
Related substances		Ph. Eur.
A 300 / A 326 nm	≤ 0.60	
A 350 / A 326 nm	≤ 0.54	
A 370 / A 326 nm	≤ 0.14	
Lead ^(*)	≤ 2 mg/kg	PM01676
Cadmium(*)	≤ 1 mg/kg	PM01676
Mercury ^(*)	≤ 0.1 mg/kg	PM00934
Arsenic(*)	≤ 1 mg/kg	PM01676
Heavy metals(*)	≤ 10 mg/kg	PM01676
Residual solvent (Methanol)(*)	≤ 3000 mg/kg	PM00558
Residual solvent (including Heptane,Methyl Acetate, Isopropanol)(*)	≤ 5000 mg/kg	PM00558

 $^(^*)$ ensured by quality assurance measures and therefore tested randomly only.

The product meets the requirements of this specification.

The product is stabilized with Tocopherol.

Vitamin A-Palmitate 1.0 Mio IU/G meets the specifications of current monographs:

[&]quot;Vitamin A Concentrate (Oily Form), synthetic" of European Pharmacopoeia

[&]quot;Vitamin A" of USP and

[&]quot;Vitamin A" of FCC III

[&]quot;Vitamin A Concentrate Oil" of IP





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