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Vitamin A Capsules

DEFINITION

Vitamin A Capsules contain NLT 95.0% and NMT 120.0% of the labeled amount of vitamin A.

IDENTIFICATION

• **A.**

Sample solution: Equivalent to 6 µg/mL of retinol from Capsules in methylene chloride

Analysis: To 1 mL of *Sample solution* add 10 mL of antimony trichloride TS.

Acceptance criteria: A transient blue color appears at once.

Change to read:

• **B. Thin-Layer Chromatography**

Standard solution: 0.5 mg/mL of retinol from USP Retinyl Acetate RS or USP Retinyl Palmitate RS in methylene chloride

Sample solution: Dissolve or extract with methylene chloride the contents of a quantity of Capsules to obtain a solution with a nominal concentration of 0.5 mg/mL of retinol.

Chromatographic system

(See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL, ▲8-mm band▲ (USP 1-Aug-2019)

Developing solvent system: Cyclohexane and ether (4:1)

Spray reagent: Phosphomolybdic acid TS

Analysis: Proceed as directed in the chapter, using the *Developing solvent system*. Locate the spots on the plate using the *Spray reagent*.

Acceptance criteria: The blue-green spot formed is indicative of the presence of retinol, and its R_F value corresponds to that of the *Standard solution*. (The approximate R_F values of the predominant spots, corresponding to the different forms of retinol, are 0.1 for the alcohol form, 0.45 for the acetate form, and 0.7 for the palmitate form.)

ASSAY

• **Vitamin A Assay ⟨571⟩**

Analysis: Use the appropriate procedure described in *Vitamin A Assay ⟨571⟩, Assay, Chromatographic Methods*.

[Note—The procedure used is stated in the labeling only if *Procedure 1* is not used.]

Acceptance criteria: 95.0%–120.0%

PERFORMANCE TESTS

• **Disintegration ⟨701⟩**

Immersion fluid: Use 0.05 M acetate buffer, prepared by mixing 2.99 g of sodium acetate and 1.66 mL of glacial acetic acid with water to obtain 1000 mL of solution with a pH of 4.5 ± 0.05.

Temperature: 37 ± 2°

Time: 45 min

Acceptance criteria: Meet the requirements

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

Change to read:

• **Labeling:** Label the Capsules to indicate the form in which the vitamin is present, and to indicate the vitamin A activity in terms of the

equivalent amount of retinol in ▲µg/Capsule. Expression of the amount of vitamin A in terms of units may be added in parentheses after the mass units.[1]▲ (USP 1-Aug-2019)

• **USP Reference Standards** ⟨11⟩

USP Retinyl Acetate RS
USP Retinyl Palmitate RS

[1] Where articles are labeled in terms of units in addition to the required labeling, the relationship of the USP Units or International Units (IU) to mass is as follows: 1 USP Vitamin A Unit = 0.3 µg of *all-trans*-retinol (vitamin A alcohol) or 0.344 µg of *all-trans*-retinyl acetate (vitamin A acetate) or 0.55 µg of *all-trans*-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE).

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
VITAMIN A CAPSULES	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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