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Oil-Soluble Vitamins Tablets

DEFINITION

Change to read:

Oil-Soluble Vitamins Tablets contain 2 or more of the following oil-soluble vitamins: Vitamin A ▲ as retinyl acetate or retinyl palmitate,▲ (USP 1-May-2020) Vitamin D as Ergocalciferol (vitamin D₂) or Cholecalciferol (vitamin D₃), Vitamin E ▲ as *RRR*- or *all-rac*-alpha-tocopherol, *RRR*- or *all-rac*-alpha-tocopheryl acetate, or *RRR*- or *all-rac*-alpha-tocopheryl acid succinate,▲ (USP 1-May-2020) Phytonadione (vitamin K₁), and Beta Carotene. Tablets contain NLT 90.0% and NMT 165.0% of the labeled amount of vitamin A ▲ as retinol▲ (USP 1-May-2020) (C₂₀H₃₀O), vitamin D as cholecalciferol (C₂₇H₄₄O) or ergocalciferol (C₂₈H₄₄O), vitamin E ▲ as 2*R*-alpha-tocopherol▲ (USP 1-May-2020) (C₂₉H₅₀O₂), phytonadione (C₃₁H₄₆O₂), and beta carotene (C₄₀H₅₆).

Oil-Soluble Vitamins Tablets contain no other vitamins or any minerals. They may contain other labeled added substances that are generally recognized as safe, in amounts that are unobjectionable.

IDENTIFICATION

Add the following:

▲• **A.** The retention times of the vitamin peaks of the *Sample solutions* correspond to those of the corresponding vitamin peaks of the *Standard solutions* as obtained in the tests for *Strength*.▲ (USP 1-May-2020)

STRENGTH

[NOTE—In the following assays, where more than one assay method is given for an individual ingredient, the requirements may be met by following any one of the specified methods, with the method used being stated in the labeling only if *Method 1* is not used.]

Change to read:

• VITAMIN A, Method 1

▲ Proceed as directed in [Vitamin A Assay \(571\)](#), [Assay, Chromatographic Methods, Procedure 1](#), except for the *Sample stock solution* and *Sample solution*.▲ (USP 1-May-2020)

Sample stock solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 5 Tablets, to a container having a polytetrafluoroethylene-lined screw-cap. Add 10 mL of dimethyl sulfoxide and 15 mL of *n*-hexane, and shake for 45 min on a wrist-action shaker in a water bath maintained at 60°. [NOTE—Set up the wrist-action shaker to ensure that the contents of the container are mixed vigorously and thoroughly.] Centrifuge at 3000 rpm for 10 min, and transfer the hexane layer by means of a pipet to a 100-mL volumetric flask. Add 15 mL of *n*-hexane to the dimethyl sulfoxide layer, shake thoroughly for 5 min, and transfer the hexane layer by means of a pipet to the 100-mL volumetric flask. Repeat this extraction with 3 additional 15-mL portions of *n*-hexane. Dilute the extracts in the volumetric flask with *n*-hexane to volume.

Sample solution: Dilute a 10-mL volume of the *Sample stock solution* with *n*-hexane to obtain a solution with a concentration of 15 µg/mL of vitamin A as retinol (C₂₀H₃₀O).

▲▲ (USP 1-May-2020)

Acceptance criteria: 90.0%–165.0% of the labeled amount of vitamin A, as retinol (C₂₀H₃₀O)

Change to read:

• VITAMIN A, Method 2

▲ Proceed as directed in [Vitamin A Assay \(571\)](#), [Assay, Chromatographic Methods, Procedure 2](#).▲ (USP 1-May-2020)

Acceptance criteria: 90.0%–165.0% of the labeled amount of vitamin A, as retinol (C₂₀H₃₀O)

Change to read:

• VITAMIN A, Method 3

▲ Proceed as directed in [Vitamin A Assay \(571\)](#), [Assay, Chromatographic Methods, Procedure 3](#). ▲ (USP 1-May-2020)

Acceptance criteria: 90.0%–165.0% of the labeled amount of vitamin A, as retinol ($C_{20}H_{30}O$)

Change to read:

• **VITAMIN D (CHOLECALCIFEROL OR ERGOCALCIFEROL)**, Method 1

▲ Proceed as directed in [Vitamin D Assay \(581\)](#), [Assay, Chromatographic Methods, Procedure 1](#), except for the *Sample solution*. ▲ (USP 1-May-2020)

Sample solution: Prepare as directed for the *Sample stock solution* in *Vitamin A, Method 1*. Transfer NLT 20 mL of this solution to a suitable container, and, if necessary, evaporate under vacuum at room temperature to obtain a concentration of 2 µg/mL of cholecalciferol or ergocalciferol.

▲ ▲ (USP 1-May-2020)

Acceptance criteria: 90.0%–165.0% of the labeled amount of vitamin D as cholecalciferol ($C_{27}H_{44}O$) or ergocalciferol ($C_{28}H_{44}O$)

Change to read:

• **VITAMIN D (CHOLECALCIFEROL OR ERGOCALCIFEROL)**, Method 2

▲ Proceed as directed in [Vitamin D Assay \(581\)](#), [Assay, Chromatographic Methods, Procedure 2](#). ▲ (USP 1-May-2020)

Acceptance criteria: 90.0%–165.0% of the labeled amount of vitamin D as cholecalciferol ($C_{27}H_{44}O$) or ergocalciferol ($C_{28}H_{44}O$)

Change to read:

• **VITAMIN D (CHOLECALCIFEROL OR ERGOCALCIFEROL)**, Method 3

▲ Proceed as directed in [Vitamin D Assay \(581\)](#), [Assay, Chromatographic Methods, Procedure 3](#), except for the *Analysis*. ▲ (USP 1-May-2020)

Analysis

Samples: *Standard solution* and *Sample solution*

Measure the peak areas of vitamin D.

Calculate the percentage of the labeled amount of cholecalciferol ($C_{27}H_{44}O$) or ergocalciferol ($C_{28}H_{44}O$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of cholecalciferol or ergocalciferol from the *Sample solution*

r_S = peak area of cholecalciferol or ergocalciferol from the *Standard solution*

C_S = concentration of [USP Cholecalciferol RS](#) or [USP Ergocalciferol RS](#) in the *Standard solution* (µg/mL)

C_U = nominal concentration of cholecalciferol or ergocalciferol in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–165.0% of the labeled amount of vitamin D as cholecalciferol ($C_{27}H_{44}O$) or ergocalciferol ($C_{28}H_{44}O$)

Change to read:

• **VITAMIN E**, Method 1

▲ Proceed as directed in [Vitamin E Assay \(551\)](#), [Assay, Procedure 1](#), except for the *Sample solution* and *Analysis*. ▲ (USP 1-May-2020)

Sample solution: Prepare as directed for the *Sample stock solution* in *Vitamin A, Method 1*. Transfer NLT 20 mL of this solution to a suitable container, and, if necessary, evaporate under vacuum at room temperature to dryness. Transfer the residue to a suitable volumetric flask with the aid of methanol, and dilute with methanol to volume to obtain a concentration of 2 mg/mL of alpha-tocopherol, alpha-tocopheryl acetate, or alpha-tocopheryl acid succinate.

▲ ▲ (USP 1-May-2020)

Analysis

Samples: *Standard solution* and *Sample solution*

Measure the peak areas.

Calculate the percentage of the labeled amount of alpha-tocopherol ($C_{29}H_{50}O_2$), alpha-tocopheryl acetate ($C_{31}H_{52}O_3$), or alpha-tocopheryl acid succinate ($C_{33}H_{54}O_5$) ▲ as 2R-alpha-tocopherol ($C_{29}H_{50}O_2$) ▲ (USP 1-May-2020) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times \text{▲}F \text{▲ (USP 1-May-2020)} \times 100$$

r_U = peak area of the relevant vitamin E form from the *Sample solution*

r_S = peak area of the relevant vitamin E form from the *Standard solution*

C_s = concentration of $\blacktriangle$ all-*rac*-alpha-tocopherol from either [USP Alpha Tocopherol RS](#) or [USP Alpha Tocopheryl Acetate RS](#) or *RRR*-alpha-tocopherol from [USP Alpha Tocopheryl Acid Succinate RS](#) $\blacktriangle$ (USP 1-May-2020) in the *Standard solution* (mg/mL)

C_u = nominal concentration of the corresponding form of vitamin E $\blacktriangle$ as 2*R*-alpha-tocopherol $\blacktriangle$ (USP 1-May-2020) in the *Sample solution* (mg/mL)

$\blacktriangle F$ = conversion factor for the content of *all-*rac**-alpha-tocopherol to 2*R*-alpha-tocopherol, 1/2 (for products labeled to contain *all-*rac** vitamin E sources) and 1 (for products labeled to contain *RRR* vitamin E sources) $\blacktriangle$ (USP 1-May-2020)

Acceptance criteria: 90.0%–165.0% of the labeled amount of alpha-tocopherol ($C_{29}H_{50}O_2$), alpha-tocopheryl acetate ($C_{31}H_{52}O_3$), or alpha-tocopheryl acid succinate ($C_{33}H_{54}O_5$) as $\blacktriangle$ 2*R*-alpha-tocopherol $\blacktriangle$ (USP 1-May-2020)

Change to read:

• **VITAMIN E, Method 2**

$\blacktriangle$ Proceed as directed in [Vitamin E Assay \(551\), Assay Procedure 2](#), except for the *Analysis*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of alpha-tocopherol ($C_{29}H_{50}O_2$), alpha-tocopheryl acetate ($C_{31}H_{52}O_3$), or alpha-tocopheryl acid succinate ($C_{33}H_{54}O_5$) as 2*R*-alpha-tocopherol ($C_{29}H_{50}O_2$) in the portion of Tablets taken as follows:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times F \times 100$$

r_U = peak area of the relevant vitamin E form from the *Sample solution*

r_S = peak area of the relevant vitamin E form from the *Standard solution*

C_s = concentration of *all-*rac**-alpha-tocopherol from either [USP Alpha Tocopherol RS](#) or [USP Alpha Tocopheryl Acetate RS](#) or *RRR*-alpha-tocopherol from [USP Alpha Tocopheryl Acid Succinate RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of the corresponding form of vitamin E as 2*R*-alpha-tocopherol in the *Sample solution* (mg/mL)

F = conversion factor for the content of *all-*rac**-alpha-tocopherol to 2*R*-alpha-tocopherol, 1/2 (for products labeled to contain *all-*rac** vitamin E sources) and 1 (for products labeled to contain *RRR* vitamin E sources)

$\blacktriangle$ (USP 1-May-2020)

Acceptance criteria: 90.0%–165.0% of the labeled amount of alpha-tocopherol ($C_{29}H_{50}O_2$), alpha-tocopheryl acetate ($C_{31}H_{52}O_3$), or alpha-tocopheryl acid succinate ($C_{33}H_{54}O_5$) as $\blacktriangle$ 2*R*-alpha-tocopherol $\blacktriangle$ (USP 1-May-2020)

Change to read:

• **VITAMIN E, Method 3**

$\blacktriangle$ Proceed as directed in [Vitamin E Assay \(551\), Assay Procedure 3](#), except for the *Analysis*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of alpha-tocopherol ($C_{29}H_{50}O_2$), $\blacktriangle$ alpha-tocopheryl $\blacktriangle$ (ERR 1-May-2020) acetate ($C_{31}H_{52}O_3$), or alpha-tocopheryl acid succinate ($C_{33}H_{54}O_5$) as 2*R*-alpha-tocopherol ($C_{29}H_{50}O_2$) in the portion of Tablets taken as follows:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times F \times 100$$

r_U = peak area of the relevant vitamin E form from the *Sample solution*

r_S = peak area of the relevant vitamin E form from the *Standard solution*

C_s = concentration of *all-*rac**-alpha-tocopherol from either [USP Alpha Tocopherol RS](#) or [USP Alpha Tocopheryl Acetate RS](#) or *RRR*-alpha-tocopherol from [USP Alpha Tocopheryl Acid Succinate RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of the corresponding form of vitamin E as 2*R*-alpha-tocopherol in the *Sample solution* (mg/mL)

F = conversion factor for the content of *all-*rac**-alpha-tocopherol to 2*R*-alpha-tocopherol, 1/2 (for products labeled to contain *all-*rac** vitamin E sources) and 1 (for products labeled to contain *RRR* vitamin E sources)

$\blacktriangle$ (USP 1-May-2020)