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Compound Undecylenic Acid Ointment

Change to read:

DEFINITION

Compound Undecylenic Acid Ointment contains, either individually or in any combination, undecylenic acid, calcium undecylenate, copper undecylenate, and zinc undecylenate in a suitable ointment base. It contains NLT 90.0% and NMT 110.0% $\blacktriangle$ (USP 1-Aug-2023) of total undecylenic acid ($C_{11}H_{20}O_2$), $\blacktriangle$ which contains NLT 90.0% and NMT 110.0% of the labeled amount of zinc undecylenate ($C_{22}H_{38}O_4Zn$) and free undecylenic acid ($C_{11}H_{20}O_2$). Or it contains NLT 90.0% and NMT 110.0% of the labeled amount of calcium undecylenate ($C_{22}H_{38}O_4Ca$) or copper undecylenate ($C_{22}H_{38}O_4Cu$), if present. $\blacktriangle$ (USP 1-Aug-2023)

Add the following:

IDENTIFICATION

- **A.** The retention time of the undecylenic acid peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay for *Total Undecylenic Acid*.
- **B.** The absorbance of the *Sample solution* is similar to that of the *Standard solutions*, as obtained in the Assay for *Zinc Undecylenate*. $\blacktriangle$ (USP 1-Aug-2023)

ASSAY

Change to read:

- $\blacktriangle$ **TOTAL** $\blacktriangle$ (USP 1-Aug-2023) **UNDECYLENIC ACID**

$\blacktriangle$ **Internal standard solution:** 0.5 mg/mL of [tridecanoic acid](#) in [n-heptane](#)

Standard solution: 0.5 mg/mL of [USP Undecylenic Acid RS](#) in the *Internal standard solution* prepared as follows. Transfer 25 mg of [USP Undecylenic Acid RS](#) to a 100-mL volumetric flask, add 0.15 N [hydrochloric acid](#) to 20% of the flask volume, and heat until the sample is liquified. Cool and add a volume of the *Internal standard solution*, equivalent to 50% of the flask volume. Dilute with 0.15 N [hydrochloric acid](#) to volume and mix well. Transfer the top *n*-heptane layer to a suitable container, and dry over [sodium sulfate, anhydrous](#). Centrifuge to clarify the mixture, and use the clear supernatant.

Sample solution: Nominally 0.5 mg/mL of undecylenic acid in the *Internal standard solution* prepared as follows. Transfer about 118 mg of Ointment, equivalent to 25 mg of undecylenic acid, to a 100-mL volumetric flask; add 0.15 N [hydrochloric acid](#) to 20% of the flask volume, and heat until the sample is liquified. Cool and add a volume of the *Internal standard solution*, equivalent to 50% of the flask volume. Dilute with 0.15 N [hydrochloric acid](#) to volume. Transfer the top *n*-heptane layer to a suitable container, and dry over [sodium sulfate, anhydrous](#). Centrifuge to clarify the mixture, and use the clear supernatant.

[NOTE—Retain the bottom aqueous layer to use as the *Sample stock solution* in the Assay for *Zinc Undecylenate*.]

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.25-mm $\times$ 30-m fused-silica capillary; coated with a 0.25- μ m film of phase [G35](#)

Temperatures

Injection port: 280°

Detector: 350°

Column: See [Table 1](#).

Table 1

Initial Temperature Carrier gas: Helium Flow rate: 0.7 mL/min	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
Injection volume: 1 µL Injection type: Split, split ratio 25:1	—	100	5
System suitability 100	10	220	13
Sample: Standard solution			
[NOTE—The relative retention times for undecylenic acid and tridecanoic acid are 1.0 and 1.1, respectively.]			15
Suitability requirements			

Resolution: NLT 10 between undecylenic acid and tridecanoic acid

Tailing factor: NMT 2.0 for undecylenic acid

Relative standard deviation: NMT 1.0% for the peak response ratio of undecylenic acid to tridecanoic acid

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the concentration (C) of total undecylenic acid in the *Sample solution*:

$$\text{Result} = (R_U/R_S) \times C_S$$

R_U = peak response ratio of undecylenic acid to tridecanoic acid from the *Sample solution*

R_S = peak response ratio of undecylenic acid to tridecanoic acid from the *Standard solution*

C_S = concentration of [USP Undecylenic Acid RS](#) in the *Standard solution* (mg/mL)

Calculate the percentage of total undecylenic acid ($C_{11}H_{20}O_2$) in the Ointment taken:

$$\text{Result} = \{(C \times V)/[(W \times L_Z \times F) + (W \times L_U)]\} \times 100$$

C = concentration of total undecylenic acid in the *Sample solution*

V = volume of the *Sample solution*, 50 mL

W = weight of Ointment in the *Sample solution* (mg)

L_Z = labeled percentage of zinc undecylenate

F = conversion factor, 0.8533

L_U = labeled percentage of free undecylenic acid

[NOTE—Where the definition list references a percentage, use a decimal or %/100.]

Calculate the conversion factor:

$$\text{Result} = (2 \times M_{r1})/M_{r2}$$

M_{r1} = molecular weight of undecylenic acid, 184.28

M_{r2} = molecular weight of zinc undecylenate, 431.92

Acceptance criteria: 90.0%–110.0%▲ (USP 1-Aug-2023)

Change to read:

• ZINC UNDECYLENATE

▲ **Standard stock solution:** 50 µg/mL of zinc¹ in 0.15 N [hydrochloric acid](#)

Standard solution A: 1 µg/mL of zinc from the *Standard stock solution* in 0.15 N [hydrochloric acid](#)

Standard solution B: 1.5 µg/mL of zinc from the *Standard stock solution* in 0.15 N [hydrochloric acid](#)

Standard solution C: 2 µg/mL of zinc from the *Standard stock solution* in 0.15 N [hydrochloric acid](#)

Standard solution D: 2.5 µg/mL of zinc from the *Standard stock solution* in 0.15 N [hydrochloric acid](#)

Standard solution E: 3 µg/mL of zinc from the *Standard stock solution* in 0.15 N [hydrochloric acid](#)

Sample stock solution: Nominally 0.45 mg/mL of zinc undecylenate, equivalent to 0.07 mg/mL of zinc, in 0.15 N [hydrochloric acid](#). Use the bottom aqueous layer from the *Sample solution* in the Assay for *Total Undecylenic Acid*.