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Flax Seed Oil Capsules

DEFINITION

Flax Seed Oil Capsules are prepared with Flax Oil derived from cold-pressed flax seeds and contain NLT 95.0% of the labeled amounts of α -linolenic (C18:3 n-3), linoleic (C18:2 n-6), and oleic (C18:1 n-9) acids.

IDENTIFICATION

- A.**
Sample: A portion of oil, about 2 mL, from NLT 10 Capsules
Analysis: Transfer the *Sample* to a suitable test tube. Add 2 mL of glacial acetic acid, and warm the test tube to about 50°, while swirling, for 5 min. Cool, and add 1 drop of sulfuric acid.
Acceptance criteria: A greenish color develops.
- B. FATTY ACID PROFILE**
System suitability solution and Chromatographic system: Proceed as directed in *Strength*.
Sample solution: Proceed as directed for the *Sample solution* in *Strength*, beginning with “Transfer 80 mg” without the addition of the *Internal standard*.
Analysis: Identify the specified fatty acid methyl ester peaks by comparing them to the reference chromatogram provided with the lot of [USP Flax Seed Oil RS](#) being used. Determine the percentage of each constituent relative to the total integrated area.
Acceptance criteria: The *Sample solution* conforms to the fatty acids composition profile in [Table 1](#).

Table 1

Fatty Acid	Shorthand Notation	Percentage (%)
Palmitic acid	16:0	2.0–7.5
Stearic acid	18:0	1.0–6.0
Oleic acid	18:1 n-9	12.0–24.0
Linoleic acid	18:2 n-6	11.0–23.0
α -Linolenic acid	18:3 n-3	50.0–65.0

STRENGTH

- CONTENT OF α -LINOLENIC, LINOLEIC, AND OLEIC ACIDS**
0.5 N methanolic sodium hydroxide solution: Dissolve 2 g of sodium hydroxide in 100 mL of methanol.
Internal standard: Methyl nonadecanoate
Sample solution: Weigh NLT 10 Capsules. With a sharp blade, carefully slice open the Capsules, avoiding loss of shell material. Combine the Capsule contents in a suitable container, and mix well. Remove any adhering substance from the emptied Capsules by washing with several portions of diethyl ether, and discard the washings. Allow the empty Capsule shells to air-dry over a period of NMT 30 min, taking precautions to avoid uptake or loss of moisture. Weigh the empty Capsule shells, and calculate the average fill weight/Capsule (A_p).
Transfer 80 mg of the accurately weighed combined Capsule contents directly into a tared 30-mL screw-top glass centrifuge tube. Re-tare, and accurately weigh about 50 mg of *Internal standard*. Add 2 mL of 0.5 N methanolic sodium hydroxide solution, tightly cap, and transfer to a heating block, or another appropriate heating device. Reflux the solution until fat globules disappear (usually 5–10 min). Add 2 mL of 0.14 g/mL boron trifluoride in methanol, cap, and reflux for 2 min. Add 4 mL of chromatographic *n*-heptane, cap, and reflux for 1 min. Cool, add about 8 mL of saturated sodium chloride solution, shake, and centrifuge to separate layers. Dilute an aliquot of the upper (heptane) layer 1:8 with chromatographic *n*-heptane, and mix well.
System suitability solution: Using about 80 mg of [USP Flax Seed Oil RS](#), proceed as directed for the *Sample solution*, beginning with “Transfer 80 mg” without the addition of the *Internal standard*.
Standard solution: Directly into a tared 30-mL screw-top glass centrifuge tube accurately weigh about 50 mg of [USP Methyl Linolenate RS](#), 20 mg of [USP Methyl Linoleate RS](#), and 20 mg of [USP Methyl Oleate RS](#). Proceed as directed for the *Sample solution*, beginning with “Re-tare”.
Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))**Mode:** GC**Detector:** Flame ionization**Column:** 0.53-mm × 30-m fused silica capillary; coated with a 1.0-μm film of G16**Temperatures****Injection port:** 220°**Detector:** 260°**Column:** See [Table 2](#).**Table 2**

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
70	0	70	2
70	5	240	5

Carrier gas: Helium**Linear velocity:** 50 cm/s**Split mode:** Splitless**Injection volume:** 1 μL**System suitability****Samples:** *System suitability solution* and *Standard solution***Suitability requirements****Chromatogram similarity:** The *System suitability solution* chromatogram is similar to the reference chromatogram provided with the lot of [USP Flax Seed Oil RS](#) being used.**Resolution:** NLT 1.5 between methyl oleate and methyl stearate, *System suitability solution***Relative standard deviation:** NMT 2% for the peak area ratios of analytes to internal standard, *Standard solution***Analysis****Samples:** *Sample solution* and *Standard solution*

Identify the retention times of the relevant fatty acid methyl esters by comparing the peaks in the chromatogram of the *System suitability solution* with those in the reference chromatogram. Identify the locus for the internal standard peak by comparison of the chromatograms of the *Standard solution* and *System suitability solution*.

Calculate the content, in mg/g, of α-linolenic, linoleic, and oleic acids in the portion of the Capsule contents taken:

$$\text{Result} = (R_U/R_S) \times (A_U/A_S) \times (m_S/W) \times (M_{r1}/M_{r2})$$

R_U = peak area ratio of the relevant methyl ester to the internal standard in the *Sample solution*

R_S = peak area ratio of the relevant methyl ester to the internal standard in the *Standard solution*

A_U = weight of the *Internal standard* in the *Sample solution* (mg)

A_S = weight of the *Internal standard* in the *Standard solution* (mg)

m_S = weight of the relevant [USP Methyl Ester RS](#) in the *Standard solution* (mg)

W = weight of sample used to prepare the *Sample solution* (g)

M_{r1} = molecular weight of the relevant fatty acid (g/mol)

M_{r2} = molecular weight of the relevant fatty acid methyl ester (g/mol)

Calculate the percentage of the labeled amounts of each individual α-linolenic, linoleic, and oleic acid in the portion of Capsules taken:

$$\text{Result} = A \times A_F \times (100/L)$$

A = content of the relevant fatty acid in the portion of Capsule contents taken (mg/g)

A_F = average fill weight (g)

L = labeled content of the relevant fatty acid (mg/Capsule)

Acceptance criteria: 95.0% of the labeled amounts of α-linolenic, linoleic, and oleic acids