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Fully Hydrogenated Rapeseed Oil

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CAS RN[®]: 84681-71-0.

DEFINITION

Fully Hydrogenated Rapeseed Oil is the product obtained by refining and hydrogenating oil obtained from the seeds of *Brassica napus* and *Brassica campestris* (Fam. Cruciferae). The product is a mixture of triglycerides in which the fatty acid composition is a mixture of saturated fatty acids.

IDENTIFICATION

- **A.** It meets the requirements of the test for [Fats and Fixed Oils, Fatty Acid Composition\(401\)](#).

IMPURITIES

• ALKALINE IMPURITIES

Sample solution: Prepare a mixture of 2.0 g of Fully Hydrogenated Rapeseed Oil, 1.5 mL of alcohol, and 3.0 mL of toluene. Dissolve by gentle heating.

Analysis: To the *Sample solution* add 0.05 mL of bromophenol blue TS, and titrate with 0.01 N hydrochloric acid to a yellow endpoint.

Acceptance criteria: NMT 0.4 mL of 0.01 N hydrochloric acid is required.

- **RESIDUE ON IGNITION (281):** NMT 0.5%, when a 5-g sample of Fully Hydrogenated Rapeseed Oil is ignited at an ignition temperature of $800 \pm 25^\circ$

• LIMIT OF NICKEL

Sample solution: Weigh 5.0 g of Fully Hydrogenated Rapeseed Oil into a previously tared platinum or silica crucible. Cautiously heat the substance, and introduce into it a wick formed from twisted ashless filter paper. Ignite the wick. When the substance ignites, stop heating. After combustion, ignite in a muffle furnace at about 600° . Continue the incineration until white ash is obtained. After cooling, transfer the residue, with the aid of two 2-mL portions of diluted hydrochloric acid, to a 25-mL volumetric flask. Add 0.3 mL of nitric acid, and dilute with water to volume.

Standard stock solution: 0.2 µg/mL of nickel prepared from nickel standard solution TS and water. Prepare immediately before use.

Standard solutions: Into three identical 10-mL volumetric flasks introduce 1.0, 2.0, and 4.0 mL of *Standard stock solution*, respectively. To each flask add a 2.0-mL portion of the *Sample solution*, and dilute with water to volume.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrophotometer equipped with a graphite furnace

Absorbance: 232.0 nm

Lamp: Nickel hollow-cathode

Analysis

Samples: *Sample solution* and *Standard solutions*

Concomitantly determine the absorbances of the *Samples* at least three times each. Record the average of the steady readings for each of the *Standard solutions* and the *Sample solution*. Plot the absorbances of the *Standard solutions* and the *Sample solution* versus the added quantity of nickel. [NOTE—The *Sample solution* should be plotted as if it had a content of added nickel equivalent to 0 µg.] Extrapolate the line joining the points on the graph until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of nickel, *C*, in µg/mL, in the *Sample solution*.

Calculate the content of nickel in the portion of Fully Hydrogenated Rapeseed Oil taken:

$$\text{Result} = (C/W) \times V$$

C = concentration of nickel in the *Sample solution* (µg/mL)

W = weight of Fully Hydrogenated Rapeseed Oil (g)

V = volume of the Sample solution, 25 mL

Acceptance criteria: NMT 1 ppm

- **LIMIT OF ERUCIC ACID:** NMT 1.0%, as determined under *Specific Tests*, in the test [Fats and Fixed Oils, Fatty Acid Composition\(401\)](#).

SPECIFIC TESTS

- **FATS AND FIXED OILS, Fatty Acid Composition (401):** Fully Hydrogenated Rapeseed Oil exhibits the fatty acid composition profile shown in [Table 1](#).

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
14	0	<1.0
16	0	3–5
18	0	38–42
20	0	8–10
22	0	42–50
24	0	1.0–2.0
18	1	≤1.0
18	2	<1.0
20	1	<1.0
22 ^a	1	≤1.0

^a Erucic acid.

- **FATS AND FIXED OILS, Acid Value(401):** NMT 6.0
- **FATS AND FIXED OILS, Iodine Value(401):** NMT 4
- **FATS AND FIXED OILS, Peroxide Value(401):** NMT 2.0
- **FATS AND FIXED OILS, Unsaponifiable Matter(401):** NMT 1.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. No storage requirements specified.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
FULLY HYDROGENATED RAPESEED OIL	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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