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Behenoyl Polyoxylglycerides

DEFINITION

Behenoyl Polyoxylglycerides is a mixture of monoesters, diesters, and triesters of glycerol and monoesters and diesters of polyethylene glycols. The polyethylene glycols used have a mean molecular weight of 400. It is produced by esterification of glycerol and polyethylene glycols with behenic acid.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

- **B. Thin-Layer Chromatographic Identification Test ⟨201⟩**

  Standard solution: 50 mg/mL of USP Behenoyl Polyoxylglycerides RS in methylene chloride

  Sample solution: 50 mg/mL of Behenoyl Polyoxylglycerides in methylene chloride

  Chromatographic system

  Application volume: 10 µL

  Developing solvent system: Ether and hexanes (70:30)

  Spray reagent: 0.1-mg/mL solution of rhodamine B in alcohol

  Analysis: Proceed as directed in the chapter. Then spray the plate with *Spray reagent*, and locate the spots on the plate by examination under UV light at a wavelength of 365 nm.

  Acceptance criteria: The R_F values of the principal spots of the *Sample solution* correspond to those of the *Standard solution*.

- **C.** It meets the requirements in *Specific Tests* (see *Table 1*) for *Fats and Fixed Oils, Fatty Acid Composition ⟨401⟩*.

IMPURITIES

- **Articles of Botanical Origin, *Total Ash* ⟨561⟩**

  Sample solution: 2.0 g

  Acceptance criteria: NMT 0.1%

- **Alkaline Impurities**

  Sample: 5.0 g

  Analysis: Heat the *Sample* slightly until it melts. Add 10 mL of alcohol and 0.05 mL of bromophenol blue TS, and mix well. While the solution is still warm, titrate with 0.01 N hydrochloric acid VS to change the color to yellow.

  Acceptance criteria: NMT 1.0 mL of 0.01 N hydrochloric acid

- **Limit of Free Ethylene Oxide and Dioxane**

  Analysis: Proceed as directed in *Ethylene Oxide and Dioxane ⟨228⟩, Method I*.

  Acceptance criteria

  Ethylene oxide: NMT 1 µg/g

  Dioxane: NMT 10 µg/g

- **Limit of Free Glycerol**

  Sample: 1.2 g

  Periodic acetic acid solution: Dissolve 0.446 g of sodium periodate in 2.5 mL of a 25% (v/v) solution of sulfuric acid, and dilute with glacial acetic acid to 100.0 mL.

  Potassium iodide solution: 75 mg/mL of potassium iodide

  Titrimetric system

  (See *Titrimetry ⟨541⟩*.)

  Mode: Residual titration

  Titrant: 0.1 M sodium thiosulfate VS

  Endpoint detection: Visual

  Analysis: Dissolve the *Sample* in 25 mL of methylene chloride, heating if necessary. Cool, and add 100 mL of water and 25.0 mL of *Periodic acetic acid solution*. Shake, and allow to stand for 30 min. Add 40 mL of *Potassium iodide solution*, and allow to stand for 1 min. Add 1 mL of starch TS, and titrate the liberated iodine with *Titrant*. Perform a blank determination, and make any necessary correction. Each mL of *Titrant* is equivalent to 2.3 mg of glycerin.

  Acceptance criteria: NMT 3.0%

SPECIFIC TESTS

- **Fats and Fixed Oils,** *Acid Value* ⟨401⟩
  Sample: 2.0 g
  Acceptance criteria: NMT 4.0
- **Fats and Fixed Oils,** *Fatty Acid Composition* ⟨401⟩**:** Behenoyl Polyoxylglycerides exhibits the composition profile of fatty acids in *Table 1*.

Table 1

Carbon-Chain Length	No. of Double Bonds	Percentage (%)
12	0	≤1.0
14	0	≤1.0
16	0	≤3.0
18	0	≤5.0
20	0	≤10.0
22	0	≥83.0
22	1	≤3.0
24	0	≤3.0

Change to read:

- **Fats and Fixed Oils,** *Hydroxyl Value* ⟨401⟩
  Sample: 1.0 g
  Analysis: Proceed as directed in the chapter. If the volume of ▲0.5 N alcoholic potassium hydroxide VS▲ (ERR 1-Mar-2022) required for the titration is less than 2 mL, a more dilute titrant may be used.
  Acceptance criteria: 30–50
- **Fats and Fixed Oils,** *Peroxide Value* ⟨401⟩
  Sample: 2.0 g
  Acceptance criteria: NMT 6.0
- **Fats and Fixed Oils,** *Saponification Value* ⟨401⟩
  Sample: 2.0 g
  Acceptance criteria: 120–140
- **Water Determination,** *Method I* ⟨921⟩
  Sample: 1.0 g
  Analysis: Use anhydrous pyridine as the solvent.
  Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers, protected from heat and moisture. Store at NMT 35°.
- **Labeling:** Label it to indicate the average nominal molecular weight of polyethylene glycols used as part of the official title.
- **USP Reference Standards** ⟨11⟩
  USP Behenoyl Polyoxylglycerides RS

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

Topic/Question	Contact	Expert Committee
BEHENOYL POLYOXYLGLYCERIDES	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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