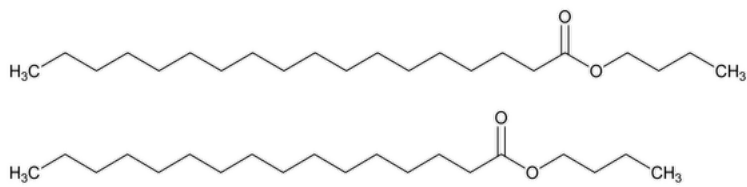


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Butyl Palmitostearate



DEFINITION
Butyl Palmitostearate is a mixture of the butyl ester of stearic acid (C₁₈H₃₆O₂) and the butyl ester of palmitic acid (C₁₆H₃₂O₂). It contains 40.0%–80.0% of butyl stearate (C₂₂H₄₄O₂). The total percentage of butyl stearate (C₂₂H₄₄O₂) and butyl palmitate (C₂₀H₄₀O₂) is NLT 90.0%.

IDENTIFICATION
• **A.** It meets the requirements of the test for *Content of Butyl Palmitate and Butyl Stearate*.

ASSAY
• **CONTENT OF BUTYL PALMITATE AND BUTYL STEARATE**
Standard solution A: 2.0 mg/mL of [USP Butyl Stearate RS](#) in chloroform
Standard solution B: 1.0 mg/mL of [USP Butyl Palmitate RS](#) in chloroform
System suitability solution: 1.4 µg/mL of [USP Butyl Stearate RS](#) and 1.0 µg/mL of [USP Butyl Palmitate RS](#) in chloroform, prepared from *Standard solution A*, *Standard solution B*, and chloroform
Sample solution: 2.0 mg/mL of Butyl Palmitostearate in chloroform
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: GC
Detector: Flame ionization
Column: 0.32-mm × 30-m capillary; bonded with a 0.25-µm layer of thickness of phase G27
Temperatures
Detector: 280°
Injection port: 280°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	—	60	2
60	4	250	20.5

Carrier gas: Helium
Flow rate: 1.4 mL/min
Injection volume: 1 µL
Injection type: Split injection, split ratio is 5:1
System suitability
Samples: *Standard solution A* and *System suitability solution*
[NOTE—The relative retention times for butyl palmitate and butyl stearate are 0.91 and 1.00, respectively.]
System suitability requirements
Resolution: NLT 20 between butyl palmitate and butyl stearate, *System suitability solution*
Tailing factor: NMT 2.0 for the butyl stearate peak, *System suitability solution*
Relative standard deviation: NMT 3.0% for the butyl stearate peak, *Standard solution A*

Analysis

Samples: *Standard solution A, Standard solution B, and Sample solution*

Identify the butyl palmitate and butyl stearate peaks in the *Sample solution* based on those in *Standard solution A* and *Standard solution B*.
Calculate the percentage of butyl palmitate or butyl stearate in the portion of Butyl Palmitostearate taken:

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

r_U = peak response of butyl palmitate or butyl stearate from the *Sample solution*

r_S = peak response of butyl palmitate from *Standard solution B* or peak response of butyl stearate from *Standard solution A*

C_S = concentration of [USP Butyl Palmitate RS](#) in *Standard solution B* or concentration of [USP Butyl Stearate RS](#) in *Standard solution A*

C_U = concentration of Butyl Palmitostearate in the *Sample solution*

Acceptance criteria

Content of butyl stearate: 40.0%–80.0%

Sum of butyl stearate and butyl palmitate: NLT 90.0%

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE, Class II\(741\)](#): 17°–24°
- [FATS AND FIXED OILS, Acid Value\(401\)](#): NMT 0.5
- [FATS AND FIXED OILS, Iodine Value\(401\)](#): NMT 1.0
- [FATS AND FIXED OILS, Saponification Value\(401\)](#): 165–180
- [WATER DETERMINATION, Method Ia\(921\)](#): NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at room temperature. Keep away from heat and sources of ignition.
- [USP REFERENCE STANDARDS \(11\)](#).
[USP Butyl Palmitate RS](#)
[USP Butyl Stearate RS](#)

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

Topic/Question	Contact	Expert Committee
BUTYL PALMITOSTEARATE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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