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Methylbenzethonium Chloride Lotion

DEFINITION
Methylbenzethonium Chloride Lotion is an emulsion containing NLT 90.0% and NMT 110.0% of the labeled amount of methylbenzethonium chloride ($C_{28}H_{44}ClNO_2 \cdot H_2O$).

IDENTIFICATION

- A.**
Sample: Suspend 0.5 mL of methylbenzethonium chloride lotion in 20 mL of water.
Analysis: Add 0.1 g of sodium carbonate, 1 mL of bromophenol blue TS, and 10 mL of chloroform to the *Sample*, and shake the mixture.
Acceptance criteria: The chloroform layer is blue.

ASSAY

- PROCEDURE**
Standard stock solution: 4.446 mg/mL of [USP Docusate Sodium RS](#) in isopropyl alcohol (equivalent to 0.01 M of [USP Docusate Sodium RS](#)).
Store this solution in a tightly-stoppered glass container. Prepare the *Standard solution* on the day of use.
Standard solution 44.46 µg/mL of [USP Docusate Sodium RS](#) in water from the *Standard stock solution* (equivalent to 0.1 mM of [USP Docusate Sodium RS](#))
Sample solution: Transfer an amount of Lotion, equivalent to 0.5 mg of methylbenzethonium chloride, to a glass-stoppered, 50-mL cylinder. Add 5 mL of chloroform (freshly purified by shaking 100 mL with 10 g of silica gel, allowing to settle, and withdrawing the supernatant), 5 mL of phosphoric acid solution (1 in 10), and 1 mL of 0.05 mg/mL of safranin O solution.
Analysis: Titrate the *Sample solution* with the *Standard solution* until 1 mL from the endpoint, then shake the stoppered tube vigorously for about 2 min, and continue the titration in 0.1-mL increments, shaking vigorously after each addition, until a pink color appears in the chloroform layer. Perform a blank determination, and make any necessary correction (see [Titrimetry \(541\)](#)). Each mL of *Standard solution* is equivalent to 48.01 µg of methylbenzethonium chloride ($C_{28}H_{44}ClNO_2 \cdot H_2O$).
Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- pH (791):** 5.2–6.0

ADDITIONAL REQUIREMENTS

- PACKAGING AND STORAGE:** Preserve in tight containers.
- USP REFERENCE STANDARDS (11).**
[USP Docusate Sodium RS](#)

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

Topic/Question	Contact	Expert Committee
METHYLBENZETHONIUM CHLORIDE LOTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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