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Benzoyl Peroxide Lotion

DEFINITION

Benzoyl Peroxide Lotion is benzoyl peroxide in a suitable lotion base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of benzoyl peroxide ($C_{14}H_{10}O_4$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile in water (5 in 10)

Internal standard solution: 3.6 mg/mL of ethyl benzoate in acetonitrile

Standard stock solution: Transfer a suitable quantity of benzoyl peroxide, recently subjected to the *Assay* under *Hydrous Benzoyl Peroxide*, in a weighed conical flask fitted with a glass stopper. Weigh again to obtain the weight of the specimen, and quantitatively dissolve in acetonitrile to obtain a solution containing 0.8 mg/mL.

Standard solution: 10 mL of *Standard stock solution* and 5 mL of *Internal standard solution*. Dilute with acetonitrile to 25 mL. This *Standard solution* contains 0.32 mg/mL of benzoyl peroxide.

Sample stock solution: Transfer the equivalent to 40 mg of benzoyl peroxide from Lotion in a 50-mL volumetric flask, and add 40 mL of acetonitrile. Shake vigorously until the material is thoroughly dispersed. Sonicate the mixture for 5 min, dilute with acetonitrile to volume, mix, and filter.

Sample solution: 10 mL of *Sample stock solution* and 5 mL of *Internal standard solution*. Dilute with acetonitrile to 25 mL.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution* (three replicate injections)

[Note—The retention times for ethyl benzoate and benzoyl peroxide are 7 and 14 min, respectively.]

Suitability requirements

Resolution: NLT 2.0 between ethyl benzoate and benzoyl peroxide

Tailing factor: NMT 2.0 for the ethyl benzoate and benzoyl peroxide peaks

Peak response ratios: The lowest and highest peak response ratios (R_S) agree within 2.0%.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of benzoyl peroxide ($C_{14}H_{10}O_4$) in the portion of Lotion taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of benzoyl peroxide to ethyl benzoate from the *Sample solution*

R_S = peak response ratio of benzoyl peroxide to ethyl benzoate from the *Standard solution*

C_S = concentration of benzoyl peroxide in the *Standard solution* (mg/mL)

C_U = nominal concentration of benzoyl peroxide in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

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Solution A: Acetonitrile and glacial acetic acid (1000:1)

Solution B: Glacial acetic acid and water (1:1000)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	18	82
20	60	40
30	60	40

System suitability solution: 100 µg/mL of benzoic acid and 60 µg/mL of methylparaben in acetonitrile

Standard solution A: 500 µg/mL of benzoic acid in acetonitrile

Standard solution B: 20 µg/mL of ethyl benzoate in acetonitrile

Standard solution C: 20 µg/mL of benzaldehyde in acetonitrile

Standard solution D: Prepare a solution of hydrous benzoyl peroxide, previously subjected to the *Assay* under *Hydrous Benzoyl Peroxide*, in acetonitrile containing the equivalent of 40 µg/mL of anhydrous benzoyl peroxide.

Sample solution: Equivalent to 100 mg of benzoyl peroxide from Lotion. In a 50-mL volumetric flask add 25 mL of acetonitrile, and shake vigorously to disperse the specimen. Sonicate for 5 min, dilute with acetonitrile to volume, mix, and filter.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1.2 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 2.0 between benzoic acid and methylparaben

Tailing factor: NMT 2.0 for the benzoic acid and methylparaben peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The responses of any peaks from the *Sample solution* corresponding to benzoic acid, ethyl benzoate, and benzaldehyde are NMT those of the main peaks from *Standard solution A* (25%), *Standard solution B* (1%), and *Standard solution C* (1%), respectively. The response of any other impurity peak from the *Sample solution*, other than the main benzoyl peroxide peak, any benzoic acid, ethyl benzoate, benzaldehyde, methylparaben, or propylparaben peak, and any solvent peak, is NMT that from *Standard solution D* (2%); and the sum of the responses of all the impurity peaks, other than those of benzoic acid, ethyl benzoate, and benzaldehyde, is NMT that from *Standard solution D* (2%).

SPECIFIC TESTS

• **pH ⟨791⟩:** 2.8–6.6

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

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

Topic/Question	Contact	Expert Committee
BENZOYL PEROXIDE LOTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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