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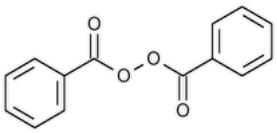
Hydrous Benzoyl Peroxide



$C_{14}H_{10}O_4$ (anhydrous) 242.23
Peroxide, dibenzoyl;
Benzoyl peroxide CAS RN®: 94-36-0; UNII: W9WZN9A0GM.

DEFINITION

Hydrous Benzoyl Peroxide contains NLT 90.0% and NMT 110.0% of the labeled amount of $C_{14}H_{10}O_4$. It contains a minimum of 20% of water for the purpose of reducing flammability and shock sensitivity.

[**Caution—**Hydrous Benzoyl Peroxide may explode at temperatures higher than 60° or cause fires in the presence of reducing substances. Store it in the original container, treated to reduce static charges.]

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 10 mg/mL of Hydrous Benzoyl Peroxide, previously subjected to the *Assay*, in methanol

Sample solution: 10 mg/mL of benzoyl peroxide in methanol

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Toluene, dichloromethane, and glacial acetic acid (50:2:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Place the plate in a developing chamber containing and equilibrated with the *Developing solvent system*. Develop the chromatogram until the solvent front has moved three-fourths of the length of the plate. Remove the plate, and allow the solvent to evaporate. Observe the plate under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

• **B.** The *Sample solution* in the test for *Organic Impurities* exhibits a major peak for benzoyl peroxide, the retention time of which corresponds to that exhibited by the *Standard solution*.

ASSAY

• **Procedure**

Sample: 300 mg of previously mixed Hydrous Benzoyl Peroxide in a conical flask fitted with a ground-glass stopper. Weigh again to obtain the weight of the *Sample*.

Analysis: Add 30 mL of glacial acetic acid, previously sparged with carbon dioxide for NLT 2 min just before use, and swirl the flask gently to dissolve. Add 5 mL of potassium iodide solution (1 in 2), and mix. Allow the solution to stand for 1 min. Titrate the liberated iodine with 0.1 N sodium thiosulfate VS. As the endpoint is approached, add 1 drop of starch iodide paste TS, or equivalent, and continue the titration to the discharge of the blue color. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩). Each mL of 0.1 N sodium thiosulfate is equivalent to 12.11 mg of $C_{14}H_{10}O_4$.

Acceptance criteria: 90.0%–110.0% of the labeled amount

IMPURITIES

Organic Impurities

• **Procedure**

Solution A: Prepare a mixture of acetonitrile and glacial acetic acid (1000:1).

Solution B: Prepare a mixture of water and glacial acetic acid (1000:1).

Mobile phase: See the gradient table below.

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: Dissolve a quantity of Hydrous Benzoyl Peroxide, previously subjected to the *Assay*, in acetonitrile to obtain a solution containing 0.32 mg/mL.

Sample solution: 0.32 mg/mL of benzoyl peroxide in acetonitrile

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 size: 10 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 2.0 between benzoic acid and methylparaben

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the area, as a percentage, of each peak in the chromatogram of the *Sample solution*:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for any individual peak other than the principal peak in the *Sample solution*

r_T = sum of the peak responses of all the individual peaks including the principal peak in the *Sample solution*

Acceptance criteria: The area of any individual peak other than the principal peak is NMT 1.5% of the total area. The sum of the areas of all peaks other than the principal peak is NMT 2.0% of the total area.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Store in the original container, at room temperature. [Note—Do not transfer Hydrous Benzoyl Peroxide to metal or glass containers fitted with friction tops. Do not return unused material to its original container, but destroy it by treatment with sodium hydroxide solution (1 in 10) until addition of a crystal of potassium iodide results in no release of free iodine.]

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

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

Chromatographic Database Information: Chromatographic Database

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