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Antipyrine, Benzocaine, and Phenylephrine Hydrochloride Otic Solution

» Antipyrine, Benzocaine, and Phenylephrine Hydrochloride Otic Solution is a solution of Antipyrine, Benzocaine, and Phenylephrine Hydrochloride in a suitable nonaqueous solvent. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of antipyrine ($C_{11}H_{12}N_2O$), benzocaine ($C_9H_{11}NO_2$), and phenylephrine hydrochloride ($C_9H_{13}NO_2 \cdot HCl$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—
USP Antipyrine RS
USP Benzocaine RS
USP Phenylephrine Hydrochloride RS

Identification—The retention times of the major peaks in the chromatograms of the *Assay preparations* correspond to those in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Assay—

Mobile phase—Mix 480 mL of acetonitrile, 3520 mL of a 0.005 M solution of sodium 1-heptanesulfonate in water, and 4 mL of phosphoric acid.

Standard preparation—Accurately weigh about 25 mg of USP Antipyrine RS, about 25 mg of USP Benzocaine RS, and about 25 mg of USP Phenylephrine Hydrochloride RS into a 250-mL volumetric flask. Add 5 mL of a 0.5 mg per mL solution of *p*-aminobenzoic acid in *Mobile phase*. Add 150 mL of *Mobile phase*, and mix to effect solution, sonicating if necessary. Dilute with *Mobile phase* to volume, and mix.

Assay preparation A—Transfer an accurately measured volume of Otic Solution, equivalent to about 100 mg of antipyrine, to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Pipet 5 mL of this solution into a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Assay preparation B—Transfer an accurately measured volume of Otic Solution, equivalent to about 100 mg of benzocaine, to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Pipet 5 mL of this solution into a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Assay preparation P—Transfer an accurately measured volume of Otic Solution, equivalent to about 5 mg of phenylephrine hydrochloride, to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 272-nm detector and a 4.6-mm × 30-cm column that contains packing L11. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.19 for *p*-aminobenzoic acid, 0.26 for phenylephrine, 0.64 for antipyrine, and 1.0 for benzocaine; the resolution, *R,* between phenylephrine and aminobenzoic acid is not less than 1.5, and the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 20 or 25 µL) of the *Standard preparation* and each of the *Assay preparations* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of antipyrine ($C_{11}H_{12}N_2O$) in each mL of the Otic Solution taken by the formula:

$$(C/V)(r_U/r_S)$$

in which C is the concentration, in µg per mL of USP Antipyrine RS in the *Standard preparation; V* is the volume, in mL, of Otic Solution taken; and r_U and r_S are the antipyrine peak responses obtained from *Assay preparation A* and the *Standard preparation*, respectively. Calculate the quantity, in mg, of benzocaine ($C_9H_{11}NO_2$) in each mL of the Otic Solution taken by the formula:

$$(C/V)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Benzocaine RS in the *Standard preparation; V* is the volume, in mL, of Otic Solution taken; and r_U and r_S are the benzocaine peak responses obtained from *Assay preparation B* and the *Standard preparation*, respectively. Calculate the quantity, in µg of phenylephrine hydrochloride ($C_9H_{13}NO_2 \cdot HCl$) in each mL of the Otic Solution taken by the formula:

$$50(C/V)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Phenylephrine Hydrochloride RS in the *Standard preparation; V* is the volume, in mL, of Otic Solution taken; and r_U and r_S are the phenylephrine peak responses obtained from *Assay preparation P* and the *Standard preparation*, respectively.

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Topic/Question	Contact	Expert Committee
ANTIPYRINE, BENZOCAINE, AND PHENYLEPHRINE HYDROCHLORIDE OTIC SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

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