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Dibucaine Hydrochloride Injection

» Dibucaine Hydrochloride Injection is a sterile solution of Dibucaine Hydrochloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of dibucaine hydrochloride ($C_{20}H_{29}N_3O_2 \cdot HCl$).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass, and protect from light.

USP Reference standards ⟨11⟩—
USP Dibucaine Hydrochloride RS

Identification—

A: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

B: Place a volume of Injection, equivalent to about 30 mg of dibucaine hydrochloride, in a suitable evaporating dish, and concentrate on a steam bath to a volume of about 10 mL. Transfer the solution to a separator, render distinctly alkaline with 1 N sodium hydroxide, and extract with four 20-mL portions of ether. Wash the combined ether extracts with 5 mL of water, discarding the washing. Evaporate the ether extracts with the aid of a current of air to dryness, and dry the residue over phosphorus pentoxide for 3 hours: the dibucaine so obtained melts between 62° and 65°.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 35.7 USP Endotoxin Units per mg of dibucaine hydrochloride.

pH ⟨791⟩: between 4.5 and 7.0.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay* under *Dibucaine*.

Standard preparation—Transfer about 50 mg of USP Dibucaine Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, add an accurately measured volume of water, equivalent to the volume of Injection taken to prepare the *Assay preparation*, dilute with methanol to volume, and mix. Where the *Assay preparation* is prepared in a 50-mL volumetric flask, transfer about 25 mg of USP Dibucaine Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, add an accurately measured volume of water, equivalent to twice the volume of Injection taken to prepare the *Assay preparation*, dilute with methanol to volume, and mix. Pass through a suitable filter having a 0.5-µm or finer porosity.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 50 mg of dibucaine, to a 100-mL volumetric flask. Dilute with methanol to volume, and mix. Where the Injection is labeled to contain 1 mg or less of dibucaine hydrochloride per mL, transfer an accurately measured volume of Injection, equivalent to about 13 mg of dibucaine hydrochloride, to a 50-mL volumetric flask, dilute with methanol to volume, and mix. Pass through a suitable filter having a 0.5-µm or finer porosity.

Procedure—Separately inject equal volumes (about 10 µL, or 20 µL where the concentration of dibucaine hydrochloride is about 0.25 mg per mL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the area responses for the major peaks. Calculate the quantity, in mg, of dibucaine hydrochloride ($C_{20}H_{29}N_3O_2 \cdot HCl$) in each mL of the Injection taken by the formula:

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

in which C is the concentration, in mg per mL, of USP Dibucaine Hydrochloride RS in the *Standard preparation; v* is the volume, in mL, of the *Assay preparation; V* is the volume, in mL, of Injection taken; and r_U and r_S are the area responses of the dibucaine peaks obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Topic/Question	Contact	Expert Committee
DIBUCAINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

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