Cimetidine Injection

Cimetidine Injection is a sterile solution of Cimetidine Hydrochloride in Water for Injection. It contains not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of C10H16N6S·HCl in the portion of Cimetidine Hydrochloride taken by the formula:

\[ 100 \times \frac{r_U}{r_S} \]

in which \( C \) is the concentration, in \( \mu \)g per mL, of USP Cimetidine Hydrochloride RS in the \( \text{Standard preparation} \); and \( r_U \) and \( r_S \) are the cimetidine peak responses obtained from the \( \text{Assay preparation} \) and the \( \text{Standard preparation} \), respectively.

**Cimetidine in Sodium Chloride Injection**

Cimetidine in Sodium Chloride Injection is a sterile solution of Cimetidine Hydrochloride and Sodium Chloride in Water for Injection. It contains not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of cimetidine (C10H16N6S) and not less than 95.0 per cent and not more than 110.0 per cent of the labeled amount of sodium chloride (NaCl).

**Packaging and storage**—Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

**USP Reference standards** (11)—
USP Cimetidine Hydrochloride RS
USP Endotoxin RS

**Identification**—
A: The chromatogram obtained from the \( \text{Assay preparation} \) exhibits a major peak for cimetidine, the retention time of which corresponds to that of the cimetidine peak in the chromatogram of the \( \text{Standard preparation} \), as obtained in the \( \text{Assay} \).

B: It responds to the tests for \( \text{Sodium (191)} \) and for \( \text{Chloride (191)} \).

**Bacterial endotoxins** (85)—It contains not more than 0.5 USP Endotoxin Unit per mg of cimetidine hydrochloride.

**pH** (791): between 5.0 and 7.0.

**Other requirements**—It meets the requirements under \( \text{Injections (1)} \).

**Assay for cimetidine**—
Mobile phase, \( \text{Standard preparation} \), and Chromatographic system—Proceed as directed in the \( \text{Assay under Cimetidine Hydrochloride} \).

**Assay preparation**—Transfer an accurately measured volume of Injection, equivalent to 2 mg of cimetidine, to a 200-mL volumetric flask, dilute with \( \text{Mobile phase} \) to volume, and mix.

**Procedure**—Separately inject equal volumes (about 50 \( \mu \)L) of the \( \text{Standard preparation} \) and the \( \text{Assay preparation} \) into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the quantity, in mg, of C10H16N6S in each mL of the Injection taken by the formula:

\[ 200 \times \frac{252.34/288.81}{C} \times \frac{V}{r_U/r_S} \]

in which 252.34 and 288.81 are the molecular weights of cimetidine and cimetidine hydrochloride, respectively; \( C \) is the concentration, in mg per mL, of USP Cimetidine Hydrochloride RS in the \( \text{Standard preparation} \); \( V \) is the volume of Injection taken; and \( r_U \) and \( r_S \) are the cimetidine peak responses obtained from the \( \text{Assay preparation} \) and the \( \text{Standard preparation} \), respectively.

**Assay for sodium chloride**—Dilute an accurately measured volume of Injection, equivalent to 2 mg of sodium chloride, to a 200-mL volumetric flask, dilute with \( \text{Mobile phase} \) to volume, and mix.

**Procedure**—Separately inject equal volumes (about 50 \( \mu \)L) of the \( \text{Standard preparation} \) and the \( \text{Assay preparation} \) into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the quantity, in mg, of sodium chloride (NaCl) in each mL of the Injection taken by the formula:

\[ 200 \times \frac{252.34/288.81}{C} \times \frac{V}{r_U/r_S} \]

in which 252.34 and 288.81 are the molecular weights of cimetidine and cimetidine hydrochloride, respectively; \( C \) is the concentration, in mg per mL, of USP Cimetidine Hydrochloride.