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Ketamine Hydrochloride Injection

» Ketamine Hydrochloride Injection is a sterile solution of Ketamine Hydrochloride in Water for Injection. It contains an amount of ketamine hydrochloride ($C_{13}H_{16}ClNO \cdot HCl$) equivalent to not less than 95.0 percent and not more than 105.0 percent of the labeled amount of ketamine ($C_{13}H_{16}ClNO$).

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

USP REFERENCE STANDARDS (11)—
[USP Ketamine Hydrochloride RS](#)

Identification—

A: The UV absorption spectrum, measured in the region between 250 and 350 nm, of a dilution of Injection in 0.01 N methanolic sodium hydroxide containing ketamine hydrochloride equivalent to about 800 µg of ketamine per mL, exhibits maxima and minima at the same wavelengths as that of a similar preparation of [USP Ketamine Hydrochloride RS](#), concomitantly measured.

B: The UV absorption spectrum of the solution employed for measurement of absorbance of the assay solution, prepared as directed in the Assay, exhibits maxima and minima at the same wavelengths as that of the Standard solution, prepared as directed in the Assay.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.4 USP Endotoxin Unit per mg of ketamine hydrochloride.

pH (791): between 3.5 and 5.5.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—Transfer an accurately measured volume of Injection, equivalent to about 500 mg of ketamine hydrochloride, to a 200-mL volumetric flask, dilute with water to volume, and mix. Transfer 20.0 mL of this solution to a 125-mL separator, add 3 mL of 0.1 N sodium hydroxide, and extract with three 15-mL portions of chloroform. Collect the chloroform extracts in a second 125-mL separator, and extract with three 30-mL portions of 0.1 N sulfuric acid, collecting the acid extracts in a 200-mL volumetric flask. Dilute with 0.1 N sulfuric acid (saturated with chloroform) to volume, and mix. Concomitantly determine the absorbances of this solution and a Standard solution of [USP Ketamine Hydrochloride RS](#) in the same medium having a known concentration of about 250 µg per mL, in 1-cm cells at the wavelength of maximum absorbance at about 269 nm, with a suitable spectrophotometer, using 0.1 N sulfuric acid (saturated with chloroform) as the blank. Calculate the quantity, in mg, of ketamine ($C_{13}H_{16}ClNO$) in each mL of the Injection taken by the formula:

$$(237.73/274.19)(2C/V)(A_U/A_S)$$

in which 237.73 and 274.19 are the molecular weights of ketamine and ketamine hydrochloride, respectively; C is the concentration, in µg per mL, of [USP Ketamine Hydrochloride RS](#) in the Standard solution; V is the volume, in mL, of Injection taken; and A_U and A_S are the absorbances of the solution from the Injection and the Standard solution, respectively.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
KETAMINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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