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Add the following:

^Ketamine Compounded Oral Solution

DEFINITION
Ketamine Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of ketamine ($C_{13}H_{16}ClNO$).
Prepare Ketamine Compounded Oral Solution 5 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Ketamine (as Ketamine Hydrochloride)	0.5 g (0.58 g)
Sodium Chloride	0.2 g
Purified Water	30 mL
Mucolox, ^a a sufficient quantity to make	100 mL

^a PCCA, Houston, TX.

In an appropriately sized calibrated container, add *Ketamine Hydrochloride* and *Sodium Chloride* to 30 mL of *Purified Water*. Stir until homogenous. Add sufficient *Mucolox* to bring to final volume, and stir until dissolved.

ASSAY

• **PROCEDURE**

Solution A: 2.76 g/L of monobasic sodium phosphate monohydrate. Filter.

Mobile phase: See [Table 1](#).

Diluent: [Water](#) and 1.0 N hydrochloric acid (50:1)

Table 1

Time (min)	Solution A (%)	Methanol (%)
0	70	30
4	70	30
5	40	60
8	40	60
8.1	70	30
12	70	30

Standard solution: 0.05 mg/mL of ketamine prepared from [USP Ketamine Hydrochloride RS](#) in *Diluent*

Sample solution: Transfer 2 mL of the Oral Solution into a 200-mL volumetric flask, add approximately 160 mL of *Diluent*, and vortex. Sonicate for 10 min. Dilute with *Diluent* to volume.

Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 210 nm**Column:** 4.6-mm × 10-cm; 2.6-μm packing [L1](#)**Column temperature:** 30°**Flow rate:** 1 mL/min**Injection volume:** 10 μL**System suitability****Sample:** *Standard solution*

[NOTE—The typical retention time for ketamine is about 3.6 min.]

Suitability requirements**Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 2.0% for replicate injections**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of ketamine ($C_{13}H_{16}ClNO$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of ketamine from the *Sample solution* r_S = peak response of ketamine from the *Standard solution* C_S = concentration of ketamine in the *Standard solution* (mg/mL) C_U = nominal concentration of ketamine in the *Sample solution* (mg/mL)**Acceptance criteria:** 90.0%–110.0%**SPECIFIC TESTS**

- **pH** ([791](#)): 4.5–5.5

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature
- **LABELING:** Label it to indicate that it is to be well shaken before use and to state the *Beyond-Use Date*. [NOTE—Although the preparation is a solution, the shaking is necessary due to rheological properties of the vehicle.]
- **USP REFERENCE STANDARDS** ([11](#)).
[USP Ketamine Hydrochloride RS](#) ▲ (USP 1-Dec-2021)

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

Topic/Question	Contact	Expert Committee
KETAMINE COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)**Most Recently Appeared In:**

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