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Add the following:

▲Prazosin Hydrochloride Compounded Oral Suspension

DEFINITION

Prazosin Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of prazosin ($C_{19}H_{21}N_5O_4$).
Prepare Prazosin Hydrochloride Compounded Oral Suspension 1 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Prazosin Hydrochloride capsules, ^a equivalent to	30 mg of prazosin
Ora-Blend, ^b a sufficient quantity to make	30 mL

- ^a Prazosin Hydrochloride 5-mg capsules, Mylan Pharmaceuticals Inc., Morgantown, WV.
^b Perrigo, Allegan, MI.

Empty the required number of *Prazosin Hydrochloride capsules* into a suitable container. Add a small amount of *Ora-Blend* and mix well to form a smooth paste. Add a sufficient amount of *Ora-Blend* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Ora-Blend*. Add sufficient *Ora-Blend* to bring to final volume. Shake well.

ASSAY

Change to read:

• PROCEDURE

Mobile phase: Add 1.74 g of sodium 1-pentanesulfonate and 3.64 mL of a 25% tetramethylammonium ▲hydroxide▲ (ERR 1-Mar-2019) solution to 500 mL of water. Adjust with glacial acetic acid to a pH of 5.0. Add 500 mL of methanol.
Standard solution: Transfer 21.90 mg of USP Prazosin Hydrochloride RS (equivalent to 20 mg of prazosin) to a 200-mL volumetric flask and dissolve in 20 mL of methanol. Add *Mobile phase* to volume.
Sample solution: Transfer 1.0 mL of Oral Suspension into a 10-mL volumetric flask. Dissolve in about 8 mL of methanol. Add *Mobile phase* to volume. Pass through a filter of 0.22-μm pore size.

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

Mode: LC
Detector: UV 250 nm
Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)
Column temperature: 15°
Flow rate: 1.0 mL/min
Injection volume: 10 μL

System suitability
Sample: *Standard solution*
[NOTE—The retention time for prazosin is about 10.0 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 prazosin ($C_{19}H_{21}N_5O_4$) in the portion of Oral Suspension taken

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of prazosin from the *Sample solution*

r_S = peak response of prazosin from the *Standard solution*

C_S = concentration of USP Prazosin Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of prazosin hydrochloride in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of prazosin, 383.40

M_{r2} = molecular weight of prazosin hydrochloride, 419.86

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [pH \(791\)](#): 4.6–5.6

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator
- **LABELING:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS (11).**
[USP Prazosin Hydrochloride RS](#) ▲2S (USP41)

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

Topic/Question	Contact	Expert Committee
PRAZOSIN HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION	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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