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Add the following:

▲Clonidine Hydrochloride Compounded Oral Suspension

DEFINITION

Clonidine Hydrochloride Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of clonidine hydrochloride ($C_9H_9Cl_2N_3 \cdot HCl$).

Prepare Clonidine Hydrochloride Compounded Oral Suspension 0.01 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Clonidine Hydrochloride tablets,[a] equivalent to	1 mg of clonidine hydrochloride
Ora-Blend,[b] a sufficient quantity to make	100 mL

[a] Clonidine Hydrochloride 0.2-mg tablets, Qualitest, Huntsville, AL.

[b] Perrigo, Allegan, MI.

Place the *Clonidine Hydrochloride Tablets* in a suitable container and triturate to a fine powder. 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 mortar contents pourable. Transfer 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 to mix well.

ASSAY

• **Procedure**

Solution A: 10 mM of monobasic potassium phosphate adjusted with 6 N potassium hydroxide to a pH of 8.0

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Acetonitrile (%)
0	98	2
60	98	2
60.1	70	30
75	70	30
75.1	98	2
85	98	2

Standard stock solution: 0.1 mg/mL of USP Clonidine Hydrochloride RS in water

Standard solution: Transfer 0.5 mL of the *Standard stock solution* to a 50-mL volumetric flask and dilute with water to volume.

Sample solution: Transfer 1.0 mL of Oral Suspension into a 10-mL volumetric flask and dilute with water to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L96

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for clonidine hydrochloride is about 71.3 min.]

Suitability requirements

Tailing factor: NMT 3.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clonidine hydrochloride ($C_9H_9Cl_2N_3 \cdot HCl$) in the portion of Oral Suspension taken:

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

r_U = peak response of clonidine hydrochloride from the *Sample solution*

r_S = peak response of clonidine hydrochloride from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **BEYOND-USE DATE:** NMT 14 days after the date on which it was compounded when stored at controlled room temperature. NMT 90 days after the date on which it was compounded when stored 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 Clonidine Hydrochloride RS

▲ (USP 1-May-2020)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CLONIDINE HYDROCHLORIDE COMPOUNDED ORAL SUSPENSION	Documentary Standards Support Associate Scientific Liaison.	NBDS2020 Non-botanical Dietary Supplements

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