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Buprenorphine Compounded Buccal Solution, Veterinary

DEFINITION

Buprenorphine Compounded Buccal Solution, Veterinary, contains NLT 90.0% and NMT 110.0% of the labeled amount of buprenorphine ($C_{29}H_{41}NO_4$).

Prepare Buprenorphine Compounded Buccal Solution, Veterinary 3 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Buprenorphine (as hydrochloride)	30 mg (32.4 mg)
Dextrose	500 mg
Sodium Citrate (anhydrous)	20 mg
Citric Acid Monohydrate	25 mg
Purified Water, a sufficient quantity to make	10 mL

Dissolve the *Dextrose*, *Sodium Citrate Anhydrous,* and *Citric Acid Monohydrate* in 5 mL of *Purified Water* in a suitable calibrated container. Add the *Buprenorphine hydrochloride* powder into the mixture and add sufficient *Purified Water* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 10 mM ammonium acetate (80:20)

Standard solution: 0.3 mg/mL of buprenorphine prepared from USP Buprenorphine Hydrochloride RS in methanol

Sample solution: Transfer 1 mL of Buccal Solution, Veterinary into a 10-mL volumetric flask, dilute with methanol to volume, and mix well.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 2.1-mm × 5-cm; 5-µm packing L7

Column temperature: 40°

Flow rate: 0.25 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for buprenorphine is about 5.8 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 buprenorphine ($C_{29}H_{41}NO_4$) in the portion of Buccal Solution, Veterinary taken:

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

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

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

C_S = concentration of buprenorphine in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.5–4.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at 2°–8°.

• **Labeling:** Label it to indicate that it is for veterinary use only. Label to indicate that it is for buccal administration, and to state the *Beyond-Use Date*.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at 2°–8°

• **USP Reference Standards** ⟨11⟩

USP Buprenorphine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
BUPRENORPHINE COMPOUNDED BUCCAL SOLUTION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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