record the chromatogram, and measure the response for the major peak. Calculate the quantity of $C_{15}H_{11}ClN_2O_2$ dissolved in comparison with a similarly chromatographed Standard solution having a known concentration of USP Oxazepam RS in 0.1 N hydrochloric acid. [NOTE—A volume of alcohol not exceeding 10% of the final total volume of the Standard solution may be used to dissolve the Reference Standard.]

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{15}H_{11}ClN_2O_2$ is dissolved in 60 minutes.

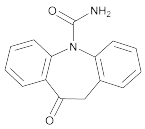
Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of oxazepam, to a medium-porosity, sintered-glass funnel that is fitted into a small suction flask. Add 25 mL of alcohol, mix with the aid of a stirring rod, and after about 5 minutes apply gentle suction to remove the extract. Repeat the extraction with four additional 25-mL portions of alcohol, transfer the extracts to a 250-mL volumetric flask, dilute with alcohol to volume, and mix. Transfer 2.0 mL of this solution to a 100-mL volumetric flask, dilute with alcohol to volume, and mix. Concomitantly determine the absorbances of this solution and of a Standard solution of USP Oxazepam RS in the same medium having a known concentration of about 4 µg per mL in 1-cm cells at the wavelength of maximum absorbance at about 229 nm, with a suitable spectrophotometer, using alcohol as the blank. Calculate the quantity, in mg, of $C_{15}H_{11}ClN_2O_2$ in the portion of Tablets taken by the formula:

$$12.5C(A_U / A_S)$$

in which C is the concentration, in µg per mL, of USP Oxazepam RS in the Standard solution, and A_U and A_S are the absorbances of the solution from the Tablets and the Standard solution, respectively.

Oxcarbazepine



$C_{15}H_{12}N_2O_2$ 252.27

5*H*-Dibenz[*b*,*f*]azepine-5-carboxamide, 10,11-dihydro-10-oxo-; 10,11-Dihydro-10-oxo-5*H*-dibenz[*b*,*f*]azepine-5-carboxamide [28721-07-5].

DEFINITION

Oxcarbazepine contains NLT 98.0% and NMT 102.0% of $C_{15}H_{12}N_2O_2$, calculated on the anhydrous basis.

IDENTIFICATION

- **A. INFRARED ABSORPTION** ⟨**197K**⟩ [NOTE—If the spectrum obtained shows differences, dissolve the substance to be examined in chloroform, and evaporate to dryness. Compare the spectrum of the residue to that of a similarly prepared USP Oxcarbazepine RS.]
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **PROCEDURE**

Buffer: 6.8 g/L of monobasic potassium phosphate in water. For each L prepared add 2 mL of triethylamine and mix. Adjust with phosphoric acid to a pH of 6.0 ± 0.1.
Mobile phase: Methanol, acetonitrile, and *Buffer* (11:8:31)
Standard solution: 0.1 mg/mL of USP Oxcarbazepine RS in *Mobile phase*
Sample solution: 0.1 mg/mL of Oxcarbazepine in *Mobile phase*
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 215 nm
Column: 4.6-mm × 25-cm; 5-µm packing L1
Column temperature: 50°
Flow rate: 1.5 mL/min
Injection size: 10 µL
System suitability
Sample: *Standard solution*
Suitability requirements:
Relative standard deviation: NMT 2.0%
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of $C_{15}H_{12}N_2O_2$ in the portion of Oxcarbazepine taken:

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

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of USP Oxcarbazepine RS in the *Standard solution* (mg/mL)
C_U = concentration of Oxcarbazepine in the *Sample solution* (mg/mL)
Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

Inorganic Impurities

- **RESIDUE ON IGNITION** ⟨**281**⟩**:** NMT 0.1%
- **HEAVY METALS,** *Method II* ⟨**231**⟩**:** 10 ppm

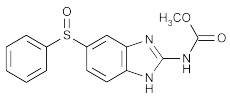
SPECIFIC TESTS

- **WATER DETERMINATION,** *Method Ia* ⟨**921**⟩**:** NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Oxcarbazepine RS

Oxfendazole



$C_{15}H_{13}N_3O_3S$ 315.35

Carbamic acid, 5-(phenylsulfinyl)-1*H*-benzimidazol-2-yl-, methyl ester.

Methyl 5-(phenylsulfinyl)-2-benzimidazolecarbamate [53716-50-0].

» Oxfendazole contains not less than 98.0 percent and not more than 100.5 percent of $C_{15}H_{13}N_3O_3S$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed, light-resistant containers.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩**—**
USP Fenbendazole RS
USP Oxfendazole RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: The appearance of the principal spot in the chromatogram of the *Test solution* corresponds to that in the chromato-