and dilute with *Diluent* to 100 mL. Dilute 1 mL of this solution to 5 mL with a 1:1 solution of *Buffer* and *Solution A*.

System suitability

Samples: *Standard solution A* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 2.0 between hydrochlorothiazide and benzothiadiazine related compound A, *Standard solution A*

Relative standard deviation: NMT 2.0% for both the telmisartan and hydrochlorothiazide peaks, *Standard solution A*

Signal-to-noise ratio: NLT 3.0 for the telmisartan, hydrochlorothiazide, and benzothiadiazine related compound A peaks from the *Sensitivity solution*

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Calculate the percentage of benzothiadiazine related compound A in the portion of Tablets taken:

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

r_U = peak response of benzothiadiazine related compound A from the *Sample solution*

r_S = peak response of benzothiadiazine related compound A from *Standard solution B*

C_S = concentration of USP Benzothiadiazine Related Compound A RS in *Standard solution B* (mg/mL)

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

Calculate the percentage of each unspecified degradation impurity related to hydrochlorothiazide in the portion of Tablets taken:

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

r_U = peak response of each unspecified degradation impurity at 270 nm from the *Sample solution*

r_S = peak response of hydrochlorothiazide from *Standard solution A*

C_S = concentration of USP Hydrochlorothiazide RS in *Standard solution A* (mg/mL)

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

Calculate the percentage of each unspecified degradation impurity related to telmisartan in the portion of Tablets taken:

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

r_U = peak response of each unspecified degradation impurity at 298 nm from the *Sample solution*

r_S = peak response of telmisartan from *Standard solution A*

C_S = concentration of USP Telmisartan RS in *Standard solution A* (mg/mL)

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

Acceptance criteria

Individual impurities: NMT 1.0% of benzothiadiazine related compound A and NMT 0.2% of each individual unspecified degradation impurity related to hydrochlorothiazide or telmisartan

Total impurities: NMT 0.2% of the sum of all degradation products related to telmisartan and NMT 1.5% of the sum of all hydrochlorothiazide degradation products

ADDITIONAL REQUIREMENTS

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

USP Benzothiadiazine Related Compound A RS
4-Amino-6-chloro-1,3-benzenedisulfonamide.
$C_6H_8ClN_3O_4S_2$ 285.73

USP Hydrochlorothiazide RS

USP Telmisartan RS

Telmisartan Tablets

DEFINITION

Telmisartan Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$).

IDENTIFICATION

- **A. ULTRAVIOLET ABSORPTION** ⟨197U⟩**:** The spectrum of the solution under test corresponds to that of the *Standard solution*, as obtained in the test for *Dissolution*.
- **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**

Diluent: 0.005 N methanolic solution of sodium hydroxide

Buffer: 2.0 g/L ammonium dihydrogen phosphate. Adjust with 1 M phosphoric acid to a pH of 3.0.

Mobile phase: Methanol and *Buffer* (70:30)

Standard stock solution: 0.8 mg/mL of USP Telmisartan RS and 0.1 mg/mL of USP Telmisartan Related Compound A RS in *Diluent*

Standard solution: 0.11 mg/mL of USP Telmisartan RS and 0.013 mg/mL of USP Telmisartan Related Compound A RS in *Mobile phase*. Pass the solution through a membrane filter of 0.45-µm pore size.

Sample solution: Transfer NLT 20 Tablets into a suitable volumetric flask, and add about 80% of the volume of *Diluent*. Swirl to disperse, and sonicate for about 10 min. Allow to cool to room temperature, dilute with *Diluent* to volume, and mix. Pass the resulting solution through a membrane filter of 0.45-µm pore size. Further dilute quantitatively in *Mobile phase* to prepare a solution having a concentration of 0.11 mg/mL.

Chromatographic system

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

Mode: LC

Detector: UV 298 nm

Column: 4.0-mm × 4-cm; 5-µm, packing L1

Column temperature: 40°

Flow rate: 0.7 mL/min

Injection size: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3 between telmisartan and telmisartan related compound A

Tailing factor: NMT 2.0 for the telmisartan peak

Capacity factor: NLT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of telmisartan ($C_{33}H_{30}N_4O_2$) in the portion of Tablets taken:

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

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

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

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

C_U = nominal concentration of telmisartan in the *Sample solution* (mg/mL)
Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- **DISSOLUTION** ⟨**711**⟩
Medium: pH 7.5 phosphate buffer (prepared by dissolving 13.61 g of potassium dihydrogen phosphate in about 800 mL of water, adjusting with 2 M sodium hydroxide to a pH of 7.5, and diluting with water to 1000 mL); 900 mL
Apparatus 2: 75 rpm
Time: 30 min
Standard solution: Transfer about 44 mg of USP Telmisartan RS to a 100-mL volumetric flask. Add 1 mL of 0.1 M sodium hydroxide, and dilute with methanol to volume. Dilute this solution quantitatively with *Medium* to obtain a solution having a final concentration of about 0.011 mg/mL.
Sample solution
For Tablets labeled to contain 20 mg: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Further dilute the filtrate with *Medium* (1:2).
For Tablets labeled to contain 40 mg: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Further dilute the filtrate with *Medium* (1:4).
For Tablets labeled to contain 80 mg: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Further dilute the filtrate with *Medium* (1:8).
Detector: UV *296* nm
Blank: *Medium*
Determine the percentage of telmisartan ($C_{33}H_{30}N_4O_2$) dissolved:

$$\text{Result} = (A_U \times C_S \times V \times 100)/(A_S \times D \times L)$$

A_U = absorbance of the *Sample solution*
C_S = concentration of the *Standard solution* (mg/mL)
V = volume of *Medium*, 900 mL
A_S = absorbance of the *Standard solution* (ERR 1-Jul-2012)
D = dilution factor of the *Sample solution*
L = label claim (mg/Tablet)
Tolerances: NLT 75% (*Q*) of the labeled amount of telmisartan ($C_{33}H_{30}N_4O_2$) is dissolved.
- **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩**:** Meet the requirements

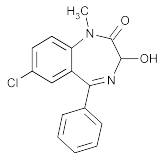
IMPURITIES
- **ORGANIC IMPURITIES**
Diluent, Buffer, Mobile phase, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.
Analysis
Sample: *Sample solution*
Calculate the percentage of each impurity in the portion of Tablets taken:

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

r_U = peak response of each individual impurity from the *Sample solution*
r_S = peak response of telmisartan from the *Sample solution*
Acceptance criteria
Individual impurities: NMT 0.2% of any individual impurity

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store at controlled room temperature.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Telmisartan RS
USP Telmisartan Related Compound A RS
1,7′-Dimethyl-2′-propyl-1*H*,3′*H*-2,5′-bibenzo[*d*]imidazole.
$C_{19}H_{20}N_4$ 304.39

Temazepam



$C_{16}H_{13}ClN_2O_2$ 300.74
2*H*-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-;
7-Chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2*H*-1,4-benzodiazepin-2-one [846-50-4].

DEFINITION
Temazepam contains NLT 98.0% and NMT 102.0% of $C_{16}H_{13}ClN_2O_2$, calculated on the dried basis. [**CAUTION—** Temazepam is a potent sedative: its powder should not be inhaled.]

IDENTIFICATION
- **A. INFRARED ABSORPTION** ⟨**197K**⟩
- **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: 2.7 g/L of monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 3.0.
Mobile phase: Acetonitrile and *Buffer* (47:53)
Diluent: Methanol and water (90:10)
Standard solution: 0.2 mg/mL of USP Temazepam RS in *Diluent*
Sample solution: 0.2 mg/mL of Temazepam in *Diluent*
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 254 nm
Column: 4-mm × 25-cm; 5-µm packing L16
Flow rate: 2 mL/min
Injection size: 10 µL
System suitability
Sample: *Standard solution*
Suitability requirements
Column efficiency: NLT 800 theoretical plates
Tailing factor: NMT 2.0
Relative standard deviation: NMT 2.0%
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of temazepam ($C_{16}H_{13}ClN_2O_2$) in the portion of sample 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 Temazepam RS in the *Standard solution* (mg/mL)