Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of acetaminophen ($C_8H_9NO_2$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Tablets taken:

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

r_U = peak response of the corresponding analyte from the *Sample solution*
r_S = peak response of the corresponding analyte from the *Standard solution*
C_S = concentration of the appropriate USP Reference Standard in the *Standard solution* (mg/mL)
C_U = nominal concentration of the appropriate analyte in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of acetaminophen ($C_8H_9NO_2$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$)

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩, *Procedure, Apparatus 1 and Apparatus 2, Immediate-Release Dosage Forms, Procedure for a pooled sample for immediate-release dosage forms*
Medium: pH 5.8 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*); 900 mL
Apparatus 2: 50 rpm
Time: 45 min
Determine the percentage of the labeled amount of acetaminophen ($C_8H_9NO_2$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) dissolved by using the following method.
Mobile phase: Proceed as directed in the *Assay*.
Standard solution: (*L*/900) mg/mL of USP Pseudoephedrine Hydrochloride RS and (*LJ*/900) mg/mL of USP Acetaminophen RS in *Medium*. [Note—*L* is the labeled quantity, in mg, of pseudoephedrine hydrochloride in each Tablet; and *J* is the ratio of the labeled quantity, in mg, of acetaminophen to the labeled quantity, in mg, of pseudoephedrine hydrochloride in each Tablet.]
Sample solution: Filtered portion of the solution under test, suitably diluted with *Medium*, if necessary
Chromatographic system and **System suitability:** Proceed as directed in the *Assay*, except to inject the *Standard solution*.
Analysis
Samples: *Standard solution* and *Sample solution*
[Note—Inject 20 µL of the *Samples*, and measure the responses for the acetaminophen and pseudoephedrine peaks.]
Calculate the percentage of the labeled amount of acetaminophen ($C_8H_9NO_2$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) dissolved:

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

r_U = peak response of the corresponding analyte from the *Sample solution*
r_S = peak response of the corresponding analyte from the *Standard solution*
V = volume of *Medium*, 900 mL
C_S = concentration of the appropriate USP Reference Standard in the *Standard solution* (mg/mL)
L = label amount of the corresponding analyte in a Tablet (mg)

Tolerances: NLT 75% (*Q*) of the labeled amount of acetaminophen ($C_8H_9NO_2$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) is dissolved.

For Tablets labeled as chewable
Medium: pH 5.8 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*); 900 mL
Apparatus 2: 75 rpm
Time: 45 min
Standard solution, Sample solution, Chromatographic system, System suitability, and **Analysis:** Proceed as directed above in *Procedure for a pooled sample for immediate-release dosage forms.*
Tolerances: NLT 75% (*Q*) of the labeled amount of acetaminophen ($C_8H_9NO_2$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

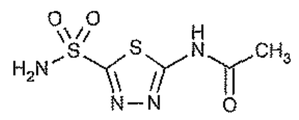
IMPURITIES

• **4-Aminophenol in Acetaminophen-Containing Drug Products** ⟨227⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
• **USP Reference Standards** ⟨11⟩
USP Acetaminophen RS
USP Pseudoephedrine Hydrochloride RS

Acetazolamide



$C_4H_6N_4O_3S_2$ 222.25
Acetamide, *N*-[5-(aminosulfonyl)-1,3,4-thiadiazol-2-yl]-; *N*-(5-Sulfamoyl-1,3,4-thiadiazol-2-yl)acetamide [59-66-5].

DEFINITION

Acetazolamide contains NLT 98.0% and NMT 102.0% of acetazolamide ($C_4H_6N_4O_3S_2$), calculated on the anhydrous basis.

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**
Mobile phase: Dissolve 4.1 g of anhydrous sodium acetate in 950 mL of water, add 20 mL of methanol and 30 mL of acetonitrile, and mix. Adjust with glacial acetic acid to a pH of 4.0.
Standard solution: 0.1 mg/mL of USP Acetazolamide RS prepared as follows. Transfer USP Acetazolamide RS into a suitable volumetric flask, add 0.5 N sodium hydroxide equivalent to 10% of the final volume, and dilute with water to volume.
Sample solution: 0.1 mg/mL of Acetazolamide prepared as follows. Transfer Acetazolamide into a suitable volumetric flask, add 0.5 N sodium hydroxide equivalent to 10% of the final volume, and dilute with water to volume.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)