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Carisoprodol and Aspirin Tablets

DEFINITION

Carisoprodol and Aspirin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amounts of carisoprodol ($C_{12}H_{24}N_2O_4$) and aspirin ($C_9H_8O_4$).

IDENTIFICATION

• **A.** The retention times of aspirin and carisoprodol from the *Sample solution* correspond to those of *Standard solution A*, as obtained in the Assay.

ASSAY

• PROCEDURE

Buffer: Combine 5 mL of glacial acetic acid and 500 mL of water, and pass the mixture through a membrane filter of 0.5- μ m or finer pore size. Use the filtrate.

Mobile phase: Methanol and *Buffer* (64:36)

Diluent: Acetonitrile, glacial acetic acid, and water (40:1:59)

Standard solution A: USP Reference Standards in *Diluent* as listed below and prepared as follows. Transfer 80 mg of [USP Aspirin RS](#) and 80J mg of [USP Carisoprodol RS](#) to a 25-mL volumetric flask. Add 15 mL of *Diluent*, swirl for 5 min, and sonicate for 25–30 s. Dilute with *Diluent* to volume.

Aspirin: 3.2 mg/mL of [USP Aspirin RS](#)

Carisoprodol: 3.2J mg/mL of [USP Carisoprodol RS](#), where J is the ratio of the labeled amount, in mg, of carisoprodol to the labeled amount of aspirin

Standard solution B: 0.016 mg/mL of [USP Salicylic Acid RS](#) in *Diluent*

System suitability solution: 0.5 mg/mL of salicylic acid in *Standard solution A*

Sample solution: Nominally 3.25 mg/mL of aspirin prepared as follows. Finely powder NLT 20 Tablets. Transfer a portion of powder, equivalent to 325 mg of aspirin, to a 100-mL volumetric flask. Add 50 mL of *Diluent*, and swirl for 5 min. Sonicate for 25–30 s, shake by mechanical means for 30 min, and dilute with *Diluent* to volume. Pass a portion of this solution through a membrane filter of 0.5- μ m or finer pore size, and use the filtrate within 8 h.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector

Aspirin and carisoprodol: Refractive index

Salicylic acid: UV 313 nm

Column: 4.6-mm $\times$ 25-cm; packing L7

Temperatures

Refractive index detector: 30 $\pm$ 1°

Column: 30 $\pm$ 1°

Flow rate: 1 mL/min

Injection volume: 50 μ L

System suitability

Samples: *Standard solution A*, *Standard solution B*, and *System suitability solution*

[NOTE—The relative retention times for aspirin, salicylic acid, and carisoprodol are about 0.6, 0.7, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.2 between solvent and aspirin; NLT 1.5 between aspirin and salicylic acid, *System suitability solution* using the refractive index detector

Relative standard deviation: NMT 2.0% for *Standard solution A* using the refractive index detector; NMT 5.0% for *Standard solution B* at 313 nm

Analysis

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

Calculate the percentages of the labeled amounts of aspirin ($C_9H_8O_4$) and carisoprodol ($C_{12}H_{24}N_2O_4$) in the portion of Tablets taken;

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

r_U = peak response of aspirin or carisoprodol from the *Sample solution*

r_S = peak response of aspirin or carisoprodol from the *Standard solution A*

C_S = concentration of [USP Aspirin RS](#) or [USP Carisoprodol RS](#) in *Standard solution A* (mg/mL)

C_U = nominal concentration of aspirin or carisoprodol in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amounts of carisoprodol ($C_{12}H_{24}N_2O_4$) and aspirin ($C_9H_8O_4$)

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Time: 45 min

Buffer: Glacial acetic acid in water (1 in 50)

Mobile phase: Methanol and *Buffer* (51:49)

Standard solution: USP Reference Standards as listed below and prepared as follows. Transfer 90 mg of [USP Aspirin RS](#) and 90J mg of [USP Carisoprodol RS](#) to a 250-mL volumetric flask. Add 5 mL of acetonitrile, previously passed through a membrane filter of 0.5-μm or finer pore size, and swirl to dissolve. Dilute with water to volume.

Aspirin: 0.36 mg/mL of [USP Aspirin RS](#)

Carisoprodol: 0.36J mg/mL of [USP Carisoprodol RS](#), where J is the ratio of the labeled amount, in mg, of carisoprodol to the labeled amount of aspirin

System suitability solution: 0.36 mg/mL of salicylic acid in the *Standard solution*

Sample solution: Filter a portion of the solution under test. Use the filtrate.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Refractive index

Column: 3.9-mm × 30-cm; packing L1

Temperatures

Detector: 30 ± 1°

Column: 30 ± 1°

Flow rate: 2 mL/min

Injection volume: 300 μL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—The relative retention times for aspirin and carisoprodol are 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between aspirin and salicylic acid; NLT 1.5 between carisoprodol and salicylic acid, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amounts of aspirin ($C_9H_8O_4$) and carisoprodol ($C_{12}H_{24}N_2O_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response of aspirin or carisoprodol from the *Sample solution*

r_S = peak response of aspirin or carisoprodol from the *Standard solution*

C_S = concentration of [USP Aspirin RS](#) or [USP Carisoprodol RS](#) in the *Standard solution* (mg/mL)

V = volume of the *Medium*, 900 mL

L = label claim of aspirin or carisoprodol (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amounts of aspirin ($C_9H_8O_4$) and carisoprodol ($C_{12}H_{24}N_2O_4$) are dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements for [Content Uniformity](#) with respect to aspirin and to carisoprodol

IMPURITIES

• **LIMIT OF FREE SALICYLIC ACID**