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# Aripiprazole Tablets

## DEFINITION

Aripiprazole Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of aripiprazole ( $C_{23}H_{27}Cl_2N_3O_2$ ).

## IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

**Standard:** Add 30 mL of [ethyl acetate](#) to 30 mg of [USP Aripiprazole RS](#). Shake for 10 min, centrifuge for NLT 5 min, and pass the supernatant through a suitable membrane filter. To the filtrate add 15 mL of [water](#), shake for 5 min, and centrifuge for NLT 10 min. Transfer 20 mL of the upper layer to a container and add [anhydrous magnesium sulfate](#), as needed. Shake well, pass through a suitable membrane filter, and evaporate the [ethyl acetate](#) on a water bath under reduced pressure. Use the residue. [NOTE—A centrifuge speed of 2000 rpm may be suitable.]

**Sample:** Grind a suitable number of Tablets and transfer a suitable portion of the ground Tablets, equivalent to 30 mg of aripiprazole, to an appropriate container. Add 30 mL of [ethyl acetate](#), shake for 10 min, centrifuge for NLT 5 min, and pass the supernatant through a suitable membrane filter. To the filtrate add 15 mL of [water](#), shake for 5 min, and centrifuge for NLT 10 min. Transfer 20 mL of the upper layer to a container and add a suitable amount of [anhydrous magnesium sulfate](#). Shake well, pass through a suitable membrane filter, and evaporate the [ethyl acetate](#) on a water bath under reduced pressure. Use the residue. [NOTE—A centrifuge speed of 2000 rpm may be suitable.]

### Analysis

**Samples:** *Standard and Sample*

**Acceptance criteria:** Meet the requirements

- **B.** The retention time of the aripiprazole peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

## ASSAY

### PROCEDURE

**Solution A:** 2.8 g/L of [anhydrous sodium sulfate](#) in [water](#)

**Mobile phase:** [Acetonitrile](#), [methanol](#), *Solution A*, and [glacial acetic acid](#) (33:11:56:1)

**Internal standard solution:** 0.33 mg/mL of [USP Propylparaben RS](#) in *Mobile phase*

**Standard stock solution:** 1 mg/mL of [USP Aripiprazole RS](#) in *Mobile phase*

**Standard solution:** 0.2 mg/mL of [USP Aripiprazole RS](#) prepared as follows. Transfer 10.0 mL of *Standard stock solution* and 10.0 mL of *Internal standard solution* to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

**Sample solution:** Nominally 0.2 mg/mL of aripiprazole from Tablets prepared as follows. Powder NLT 20 Tablets and transfer a suitable portion of the powder to an appropriate volumetric flask. Add 40% of the final flask volume of *Mobile phase* and 20% of the final flask volume of *Internal standard solution*. Shake for 10 min, and dilute with *Mobile phase* to volume. Centrifuge, if necessary, and pass the supernatant through a suitable filter of NMT 0.5- $\mu$ m pore size, discard the first 1 mL of filtrate, and use the subsequent filtrate.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm  $\times$  25-cm; 5- $\mu$ m packing [L1](#)

**Flow rate:** 1 mL/min

**Injection volume:** 10  $\mu$ L

**Run time:** NLT 2 times the retention time of aripiprazole

### System suitability

**Sample:** *Standard solution*

[NOTE—The relative retention times for aripiprazole and propylparaben are about 1.0 and 1.5, respectively.]

### Suitability requirements

**Resolution:** NLT 8 between aripiprazole and propylparaben

**Tailing factor:** NMT 1.7 for aripiprazole and for propylparaben

**Relative standard deviation:** NMT 2.0% for the peak response ratio of aripiprazole to propylparaben

### Analysis

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

Calculate the percentage of the labeled amount of aripiprazole ( $C_{23}H_{27}Cl_2N_3O_2$ ) in the portion of Tablets taken:

$$\text{Result} = (R_U / R_S) \times (C_S / C_U) \times 100$$

$R_U$  = peak response ratio of aripiprazole to propylparaben from the *Sample solution*

$R_S$  = peak response ratio of aripiprazole to propylparaben from the *Standard solution*

$C_S$  = concentration of [USP Aripiprazole RS](#) in the *Standard solution* (mg/mL)

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

**Acceptance criteria:** 95.0%–105.0%

## PERFORMANCE TESTS

**Change to read:**

- [DISSOLUTION \(711\)](#).

### Test 1

**Medium:** [pH 1.2 hydrochloric acid buffer](#) (Transfer 250 mL of 14.9 g/L of [potassium chloride](#) in [water](#) to a 1-L volumetric flask, add 425 mL of 0.2 N [hydrochloric acid](#), and dilute with [water](#) to volume. Degas the resulting solution or pass the resulting solution through a filter under vacuum.), degassed; 900 mL

**Apparatus 2:** 60 rpm

**Time:** 30 min

**Procedure:** Determine the percentage of the labeled amount of aripiprazole ( $C_{23}H_{27}Cl_2N_3O_2$ ) dissolved by using either the *Spectrometric procedure* or the *Chromatographic procedure* described below.

### Spectrometric procedure

**Standard stock solution:** 1 mg/mL of [USP Aripiprazole RS](#) in [alcohol](#)

**Standard solution:** ( $L/900$ ) mg/mL of [USP Aripiprazole RS](#) from *Standard stock solution* in *Medium*, where  $L$  is the label claim, in mg/Tablet

**Sample solution:** Pass a portion of the solution under test through a suitable filter, discarding the first 5 mL of filtrate.

### Instrumental conditions

**Mode:** UV

**Analytical wavelengths:** 249 and 325 nm

**Cell length:** 1 cm

**Blank:** *Medium*

### Analysis

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

Calculate the percentage of the labeled amount of aripiprazole ( $C_{23}H_{27}Cl_2N_3O_2$ ) dissolved:

$$\text{Result} = (A_U / A_S) \times C \times V \times (1/L) \times 100$$

$A_U$  = absorbance at 249 nm minus the absorbance at 325 nm of the *Sample solution*

$A_S$  = absorbance at 249 nm minus the absorbance at 325 nm of the *Standard solution*

$C_S$  = concentration of [USP Aripiprazole RS](#) in the *Standard solution* (mg/mL)

$V$  = volume of *Medium*, 900 mL

$L$  = label claim (mg/Tablet)

### Chromatographic procedure

**Solution A:** 2.8 g/L of [anhydrous sodium sulfate](#)

**Solution B:** 13.9 g/L of [glacial acetic acid](#) and 23.9 g/L of [sodium acetate](#) in [water](#)

**Mobile phase:** [Acetonitrile](#), [methanol](#), *Solution A*, and [glacial acetic acid](#) (40:10:50:1)

**Diluent:** *Solution B* and [methanol](#) (50:50)

**Internal standard solution:** 0.67 µg/mL of [USP Propylparaben RS](#) in *Diluent*

**Standard stock solution A:** 1 mg/mL of [USP Aripiprazole RS](#) in *Mobile phase*

**Standard stock solution B:** 0.002 mg/mL of [USP Aripiprazole RS](#) from *Standard stock solution A* in *Medium* passed through a suitable filter of NMT 0.5-µm pore size, discarding the first 6 mL of filtrate

**Standard solution:** 0.001 mg/mL of [USP Aripiprazole RS](#) from *Standard stock solution B* prepared by combining 5 mL of *Standard stock solution B* and 5 mL of *Internal standard solution*

**Sample stock solution:** Pass a portion of the solution under test through a suitable filter of NMT 0.5-µm pore size, discarding NLT the first 6 mL of filtrate.

**Sample solution:** Combine 2 mL of *Sample stock solution* with 2 mL of *Internal standard solution*.

**Chromatographic system:** Proceed as directed in the Assay except as follows.

**Injection volume:** 100 µL

**System suitability**