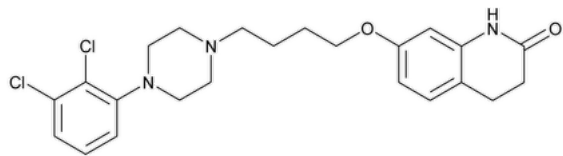


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Aripiprazole



$C_{23}H_{27}Cl_2N_3O_2$ 448.39
2(1*H*)-Quinolinone, 7-[4-[4-(2,3-dichlorophenyl)-1- piperazinyl]butoxy]-3,4-dihydro-;
7-[4-[4-(2,3-Dichlorophenyl)-1-piperazinyl]butoxy]-3,4-dihydrocarbostyryl CAS RN[®]: 129722-12-9; UNII: 82VFR53I78.

DEFINITION
Aripiprazole contains NLT 98.0% and NMT 102.0% of aripiprazole ($C_{23}H_{27}Cl_2N_3O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **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**

Protect the solutions from light.

- Diluent:** Acetonitrile, methanol, water, and acetic acid (30:10:60:1)
Solution A: Acetonitrile and 0.05% trifluoroacetic acid (10:90)
Solution B: Acetonitrile and 0.05% trifluoroacetic acid (90:10)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
2	80	20
10	65	35
20	10	90
25	10	90
26	80	20
35	80	20

[NOTE—The gradient was established on an HPLC system with a dwell volume of approximately 650 µL.]

- System suitability solution:** 1 µg/mL each of [USP Aripiprazole RS](#) and [USP Aripiprazole Related Compound F RS](#) in *Diluent*
Standard solution: 0.1 mg/mL of [USP Aripiprazole RS](#) in *Diluent*
Sample solution: 0.1 mg/mL of Aripiprazole in *Diluent*
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: LC
Detector: UV 254 nm

Column: 4.6-mm × 10-cm; 3-μm packing L1

Flow rate: 1.2 mL/min

Injection volume: 20 μL

System suitability

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

[NOTE—The relative retention times for aripiprazole and aripiprazole related compound F are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 2.0 between aripiprazole and aripiprazole related compound F, *System suitability solution*

Tailing factor: NMT 1.5 for aripiprazole, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES**

Protect the solutions from light.

Diluent, Solution A, Solution B, Mobile phase, System suitability solution, Standard solution, 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 Aripiprazole taken:

$$\text{Result} = (r_i/r_U) \times (1/F) \times 100$$

r_i = peak response of each impurity from the *Sample solution*

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

F = relative response factor (see [Table 2](#))

Acceptance criteria: See [Table 2](#).

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Aripiprazole related compound G ^a	0.9	0.72	0.10
Aripiprazole	1.0	—	—
Aripiprazole related compound F ^{b,c}	1.1	1.0	0.10
Aripiprazole 4,4'-dimer ^d	1.3	1.0	0.10
Any other individual impurity	—	1.0	0.10
Total impurities	—	—	0.50