

SPECIFICATIONS

Aripiprazole

TEST

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Description :

White to off-white crystalline powder

Solubility :

Freely soluble in Dichloromethane, sparingly soluble in Toluene, Insoluble in Methanol and Water.

Identification – IR :

The Infrared spectrum of the substance being examined should be concordant with the in-house reference sample spectrum.

Loss on Drying at $105^{\circ}\text{C} \pm 5^{\circ}\text{C}$, % w/w :

Not more than 0.5

Residue on Ignition, % w/w :

Not more than 0.1

Heavy Metals, ppm :

Not more than 20

Related Substances by HPLC

1,4-Bis(3,4-dihydro-2-1H)-quinoline-7-oxybutane, % :

Not more than 0.20

Any other impurity % :

Not more than 0.10

Total impurities % :

Not more than 0.50

Residual Solvents by GC (ppm)

a) Methanol :

Not more than 3000

b) Dichloromethane :

Not more than 600

c) Isopropylalcohol :

Not more than 5000

d) Chloroform :

Not more than 60

e) Toluene :

Not more than 890

Assay by HPLC (On dried basis), % :

Not less than 98.0 and
Not more than 102.0