

A FLU-O-CIL

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Amendment No : 02

Amendment Date : 08/01/2026

Shelf Life: 5 years

Description

Dark brown to blackish brown colour, round biconvex tablets having SDL mark on one side.

Loss on Drying at 105°

Not more than 15 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 30 min.

Hardness

Not less than 2 kg/cm²

Thickness

5.0 ± 0.5 mm

Diameter

8.0 ± 0.5 mm

Average Weight

290 mg ± 5%

Uniformity of weight

Not more than 2 tablets deviate by more than 5% of the average weight and none by more than 10% of the average weight.

Ash

Not more than 35 % w/w

Acid insoluble ash

Not more than 10 % w/w

Water soluble extractive

Not less than 30 % w/w

Alcohol soluble extractive

Not less than 2 % w/w

pH (1% Aq. solution)

7.5 – 9.0

Elemental assay

Mercury (Hg)

20 – 28 mg/tablet

Sulphur (S)

7 - 11 mg/tablet

Copper (Cu)

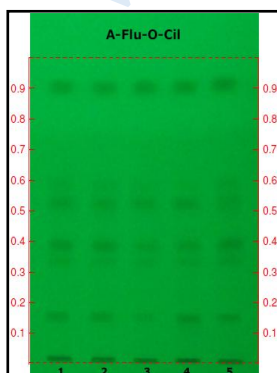
2 – 3.5 mg/tablet

Thin Layer Chromatography

Solvent system

Toluene : Ethyl acetate
(7 : 3)

Details



Solvent of Extraction – Methanol

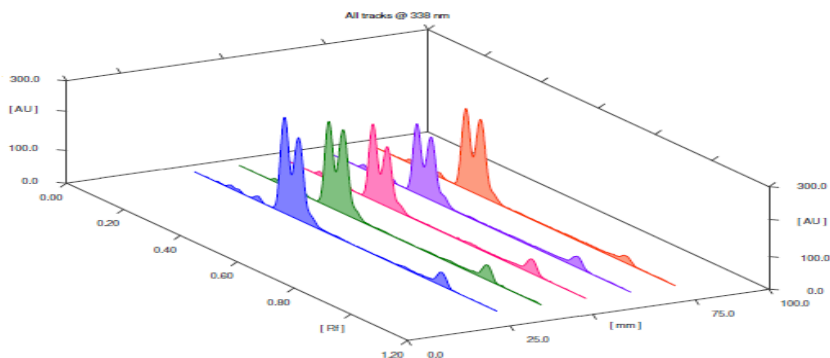
Solvent front – 90 cm

Total No. of Major spots – 6

Visualization – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Gray	0.15
2	Light Gray	0.33
3	Gray	0.39
4	Gray	0.52
5	Light Gray	0.60
6	Black	0.91



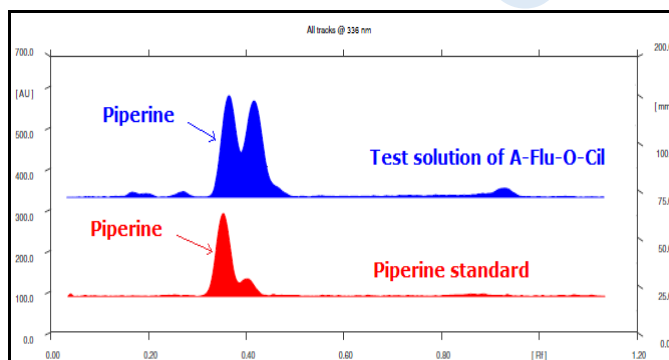
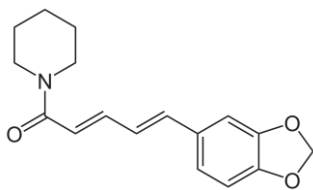


3D Peak Display of A Flu-O-Cil at 338 nm

HPTLC Profile [†]

i) Piperine

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with Piperine standard.



Acute Toxicity

Non-toxic when single dose (10 x therapeutic dose) administered orally

E. coli

Absent/g

P. aeruginosa

Absent/g

Salmonella sp.

Absent/g

Staphylococcus sp.

Absent/g

Total Microbial plate count (TPC)

Not more than 10⁵ c.f.u./g

Total Yeast & Mould count (TYMC)

Not more than 10³ c.f.u./g

Pesticide Residue [†] (OC+OP)

Complies as per API

Aflatoxins B1,B2,G1,G2 [†]

Complies as per API