

TAPYADI LOHA (WITH RAJATA)

Monograph No. – 0500114 ver 3.0

Issue No: 03

Date of Issue: 26/04/2018

Text Reference : Bharat Bhaishajya Ratnakar 2/2562

Amendment No : 01

Amendment Date : 25/01/2024

Shelf Life: 5 years

Description

Light gray to dark gray colour, round biconvex tablet having SDL mark on one side.



Loss on Drying at 105°

Not more than 7 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 30 min.

Hardness

Not less than 2 kg/cm²

Thickness

4.0 ± 0.5 mm

Diameter

8.0 ± 0.5 mm

Average Weight

270 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 55 % w/w

Acid insoluble ash

Not more than 25 % w/w

Water soluble extractive

Not less than 14.5 % w/w

Alcohol soluble extractive

Not less than 3.5 % w/w

pH (1% Aq. solution)

5.0 – 7.0

Elemental Assay

Iron (Fe)

9 – 16 mg/tab

Silver (Ag)

7 – 14 mg/tab

Copper (Cu)

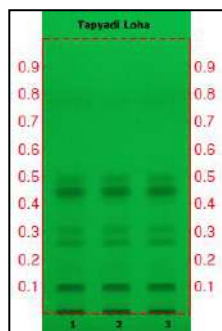
Not less than 1.2 mg/tab

Thin Layer Chromatography

Solvent system

Toluene : Ethyl acetate
(7 : 3)

Details



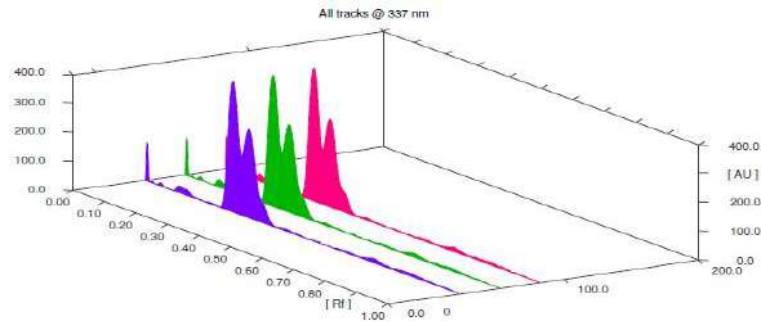
Solvent of Extraction – Methanol

Solvent front – 90 mm

Total No. of Major spots – 6

Detection – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Gray	0.10
2	Light Gray	0.19
3	Gray	0.26
4	Gray	0.31
5	Light Gray	0.43
6	Gray	0.49

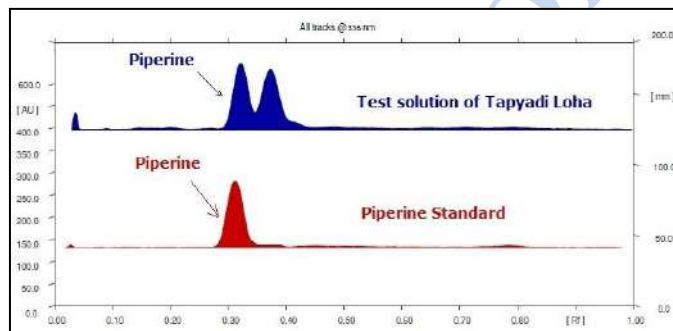
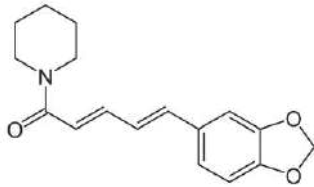


3D Peak Display of Tapyadi Loha at 337nm

HPTLC Profile[†]

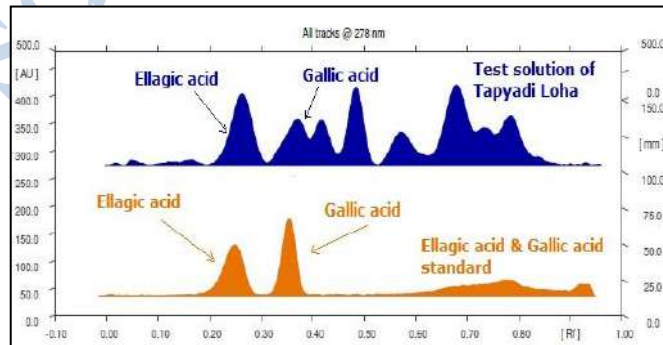
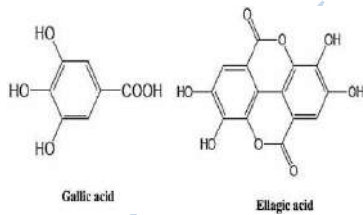
i) Piperine

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.



ii) Total Polyphenols (as Gallic acid & Ellagic acid)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid & 278 nm for Ellagic acid corresponding with Gallic acid & Ellagic acid standard.



E. coli

Absent/g

P. aeruginosa

Absent/g

Salmonella sp.

Absent/g

Staphylococcus sp.

Absent/g

Total Microbial plate count (TPC)

NMT 10⁵ c.f.u./g

Total Yeast & Mould count (TYMC)

NMT 10³ c.f.u./g

Pesticide Residue[†] (OC+OP)

Complies as per API

Aflatoxins B1,B2,G1,G2[†]

Complies as per API