

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 : 00

Amendment Date : --

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 6 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 30 min.

Hardness

Not less than 2 kg/cm²

Average Weight

270 +/- 5%

Ash

Not more than 50 % w/w

Acid insoluble ash

Not more than 20 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 5 % w/w

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)

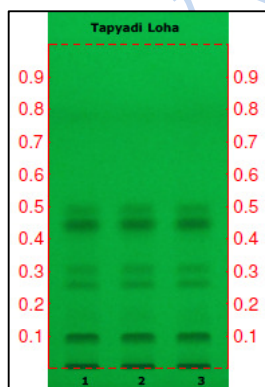
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

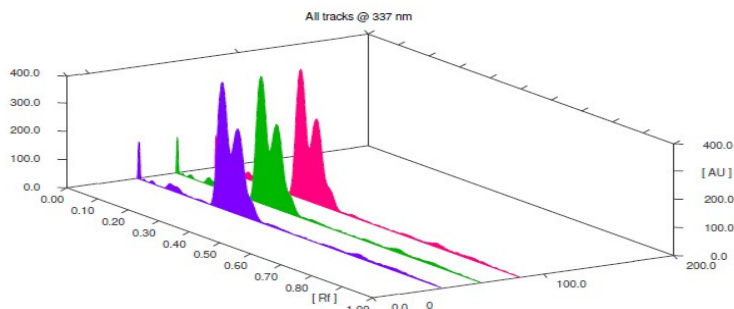
Total No. of Major spots – 6

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



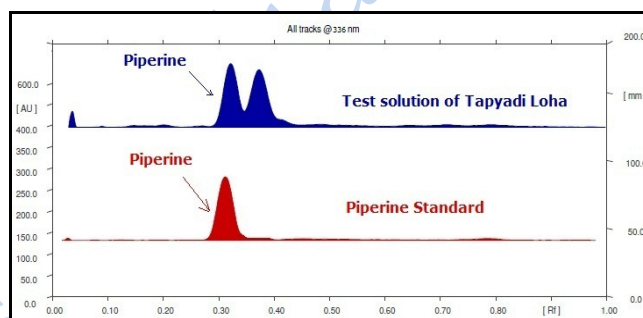
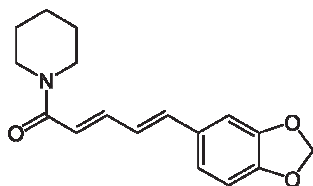


3D Peak Display of Tapyadi Loha at 337nm

HPTLC Profile

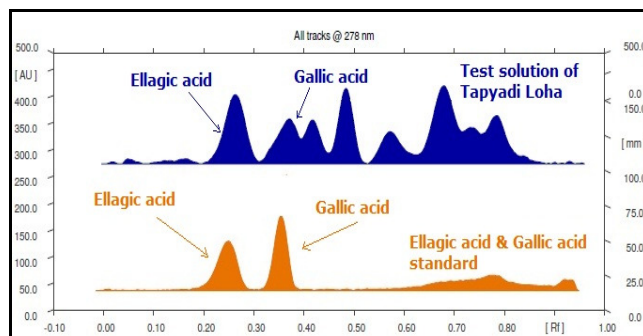
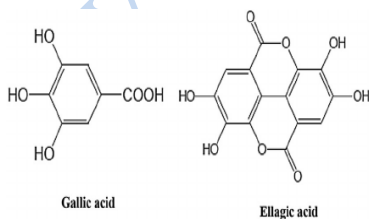
i) Piperine

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

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Note : ⁺ : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

Staphylococcus sp. [†]	Absent/g
Total Microbial plate count (TPC) [†]	NMT 10 ⁵ c.f.u./g
Total Yeast & Mould count[†]	NMT 10 ³ c.f.u./g
Pesticide Residue [†] (OC+OP)	Complies as per API
Aflatoxins B1,B2,G1,G2 [†]	Complies as per API

TAPYADI LOHA (WITH RAJATA)

Monograph No. – 050011 ver 3.0

Issue No: 03

Date of Issue: 26/04/2018

Text Reference : Bharat Bhaishajya Ratnakar 2/2562

Amendment No : 00

Amendment Date : --

Shelf Life: 10 years

Description

Dark gray to black colour powder, odour characteristic, taste slight bitter.

Loss on Drying at 105°

Not more than 5 % w/w

Ash

Not more than 50 % w/w

Acid Insoluble Ash

Not more than 35 % w/w

Water soluble extractive

Not less than 35 % w/w

pH (1% aqueous solution)

4.0 – 5.5

Bulk Density

0.7 – 1.3

Elemental Assay

Iron (Fe)

8.0 – 14.0 % w/w

Silver (Ag)

8.0 – 12.0 % w/w

Copper (Cu)

Not less than 1.0 % w/w

Thin Layer Chromatography

Solvent system

Toluene : Ethyl acetate
(7 : 3)

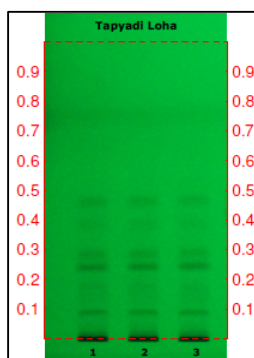
Details

Solvent of Extraction – Methanol

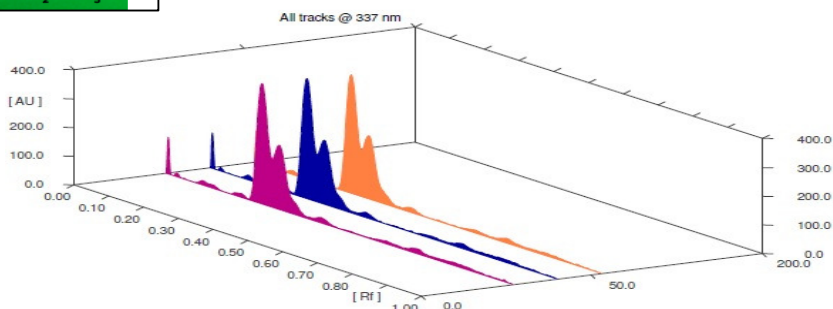
Solvent front – 90 mm

Total No. of Major spots – 6

Detection – Under UV at 254 nm



Major Spots	Colour	Approx. Rf.
1	Gray	0.09
2	Light Gray	0.19
3	Gray	0.24
4	Gray	0.29
5	Light Gray	0.39
6	Gray	0.46



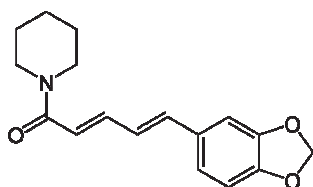
3D Peak Display of Tapyadi Loha at 337nm

Confidential - photocopy prohibited

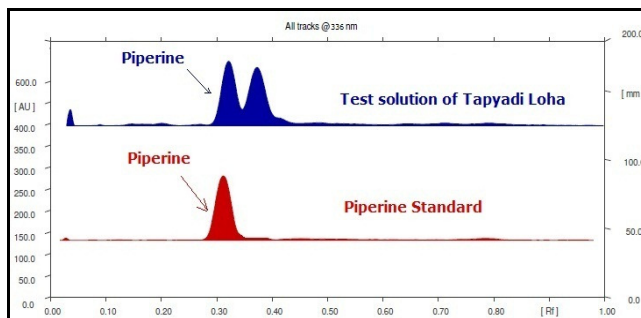
Note : [†] : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

HPTLC Profile

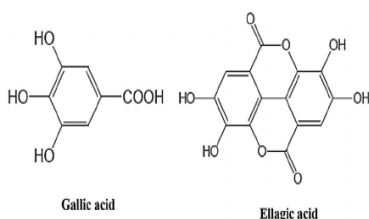
i) Piperine



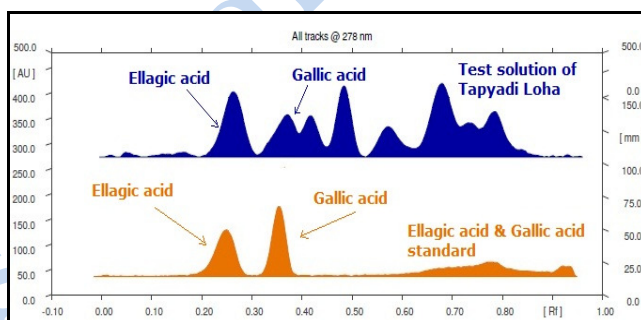
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E. coli ⁺	Absent/g
P. aeruginosa ⁺	Absent/g
Salmonella sp. ⁺	Absent/g
Staphylococcus sp. ⁺	Absent/g
Total Microbial plate count (TPC) ⁺	NMT 10 ⁵ c.f.u./g
Total Yeast & Mould count ⁺	NMT 10 ³ c.f.u./g
Pesticide Residue ⁺ (OC+OP)	Complies as per API
Aflatoxins B1,B2,G1,G2 ⁺	Complies as per API