

MANJISHTHA TABLETS

Monograph No. – 2700254 ver 3.0

Issue No: 03

Date of Issue: 23/10/2024

Text Reference: API Part I, Volume III, Monograph No. 52

Amendment No : 00

Amendment Date : --

Shelf Life: 3 years

Description

Brick red to reddish brown color caplet shape coated tablets 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 60 min.

Hardness

Not less than 2 kg/cm²

Thickness

5.5 ± 0.5 mm

Length

21.0 ± 0.5 mm

Average Weight

900 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 15 % w/w

Acid insoluble ash

Not more than 1 % w/w

Water soluble extractive

Not less than 25 % w/w

Alcohol soluble extractive

Not less than 3.5 % w/w

pH (1 % Aq. Solution)

6.0 – 8.0

Thin Layer Chromatography Solvent system

Toluene : Ethyl acetate : Formic acid : Methanol
(8 : 1 : 0.8 : 0.8)

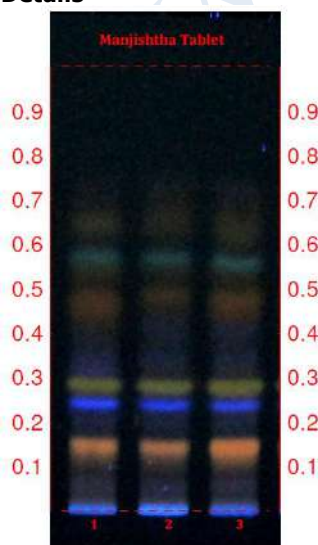
Details

Solvent of Extraction –Methanol

Solvent front – 90 mm

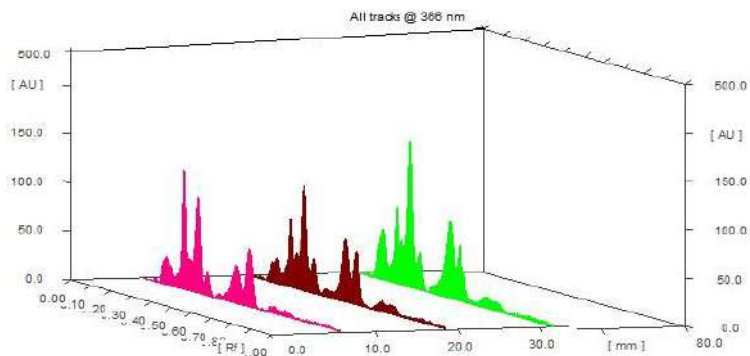
Total No. of Major spots – 6

Visualization – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Orange	0.15
2	Blue	0.25
3	Yellow	0.29
4	Light orange	0.46
5	Sky Blue	0.57
6	Light yellow	0.63



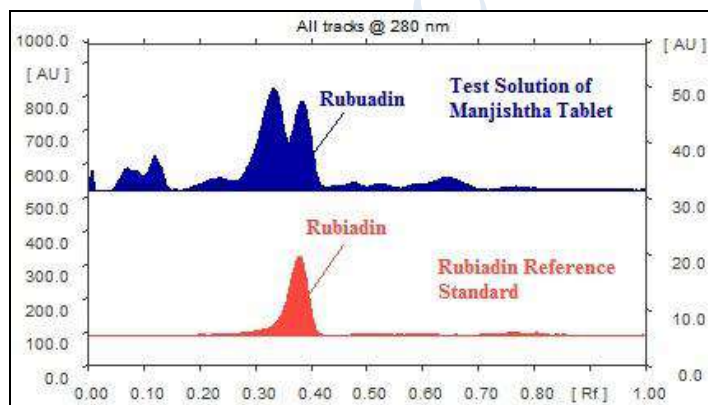
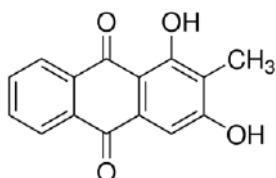


3D Peak Display of Manjishtha Tablets at 366 nm

HPTLC Profile[†]

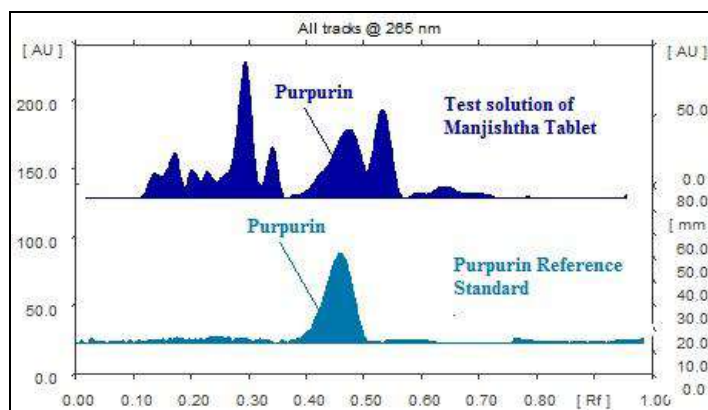
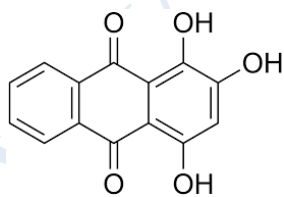
i) Rubiadin

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 280 nm corresponding with Rubiadin reference standard.



ii) Purpurin

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 265 nm corresponding with Purpurin reference standard.



Heavy metal

Lead (Pb)	Not more than 10 ppm
Mercury (Hg)	Not more than 1 ppm
Arsenic (As)	Not more than 3 ppm
Cadmium (Cd)	Not more than 0.3 ppm

<i>E. coli</i>	Absent/g
<i>P. aeruginosa</i>	Absent/g
<i>Salmonella sp.</i>	Absent/g
<i>Staphylococcus sp.</i>	Absent/g
Total Microbial plate Count (TPC)	Not more than 10 ⁵ c.f.u./g
Total Yeast & Mould count (TYMC)	Not more than 10 ³ c.f.u./g
Pesticide Residue [†] (OC+OP)	Complies as per API
Aflatoxins B1,B2,G1,G2 [†]	Complies as per API