

RADONA TABLET

Monograph No. – 070237 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 00

Amendment Date : --

Shelf Life: 5 years

Description

Dark purple coloured round, biconvex film coated tablets.

Loss on Drying at 105°

Not more than 6 % w/w

Hardness

Not less than 2.5 kg/cm²

Thickness

5.5 ± 0.5 mm

Diameter

12.0 – 12.50 mm

Disintegration Time

Not more than 60 mins

Average Weight

676 mg ± 5 %

Uniformity of weight on 20 tablets

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 32 % w/w

Acid insoluble ash

Not more than 6 % w/w

Water soluble extractive

Not less than 13 % w/w

Alcohol soluble extractive

Not less than 1 % w/w

Elemental Assay

Zinc (Zn)

6.0 – 9.0 mg/tab

Sulphur (S)

Not less than 60 mg/tab

Thin Layer Chromatography Mobile Phase

Toluene : Ethyl acetate : Formic acid
(4 : 4 : 2)

Details

Solvent of Extraction - Methanol

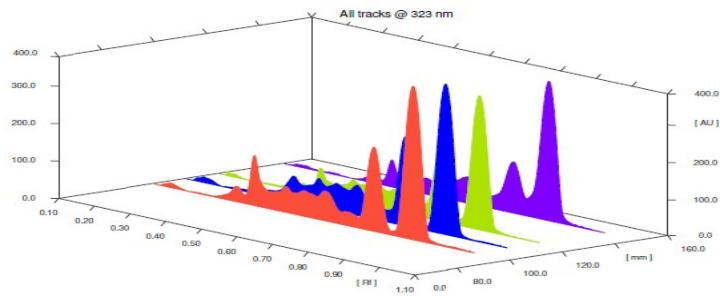
Solvent front – 90 mm

Total No. of Major spots – 4

Detection – Under UV at 366 nm

Major Spots	Colour	Approx. Rf.
1	Light Green	0.28
2	Green	0.35
3	Blue	0.51
4	Gray	0.72

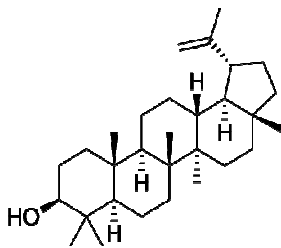




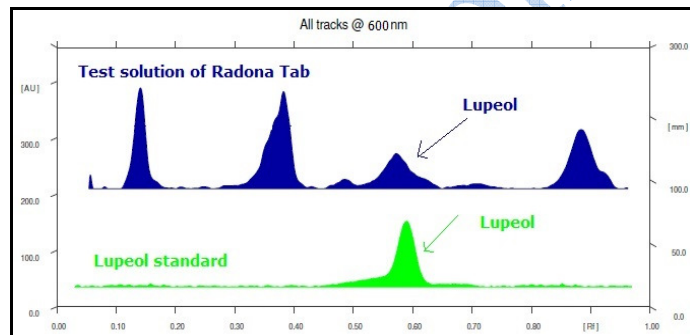
3D Peak Display of Radona Tablet at 323 nm

HPTLC Profile

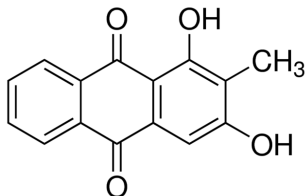
i) Lupeol



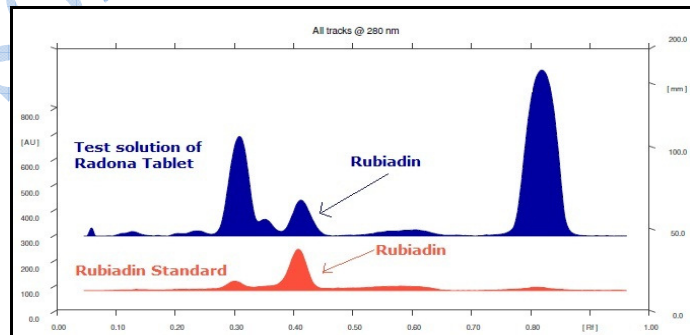
When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 600 nm corresponding with Lupeol standard.



ii) 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 standard.



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