

ASHOTONE TABLET

Monograph No. – 070205 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 red 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 - 12.5 mm

Disintegration Time

Not more than 60 min

Average Wt

676 mg ± 5 % w/w

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 8 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 4.5 % w/w

Elemental Assay

Iron (Fe)

7.0 – 10.0 mg/tab

Calcium (Ca)

Not less than 3.0 mg/tab

Thin Layer Chromatography Mobile Phase

Toluene : Ethyl acetate : Formic acid
(7 : 2 : 1)

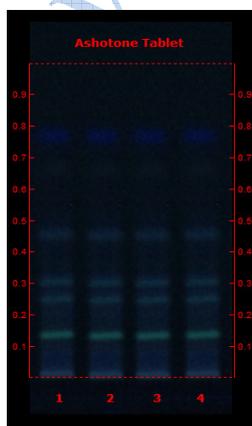
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

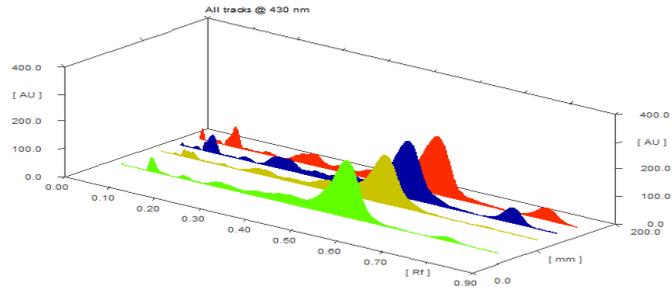
Total No. of Major spots – 5

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Green	0.14
2	Light Blue	0.25
3	Light Blue	0.31
4	Light Blue	0.45
5	Blue	0.77

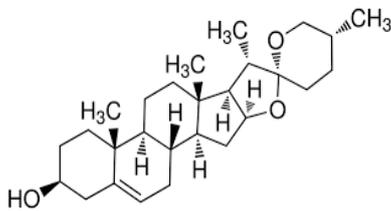




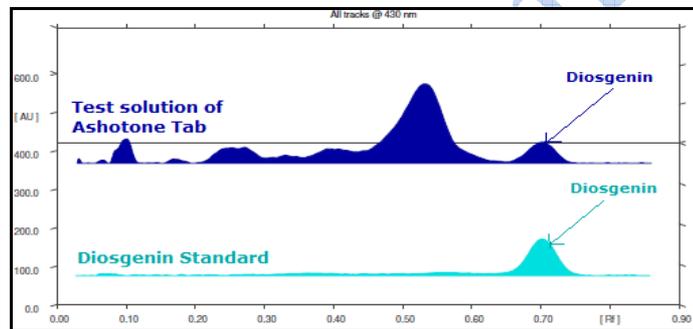
3D Peak Display of Ashotone Tablet at 430 nm

HPTLC Profile

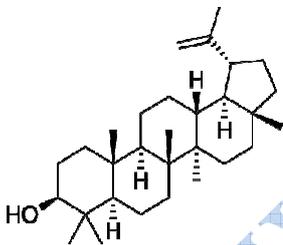
i) Diosgenin



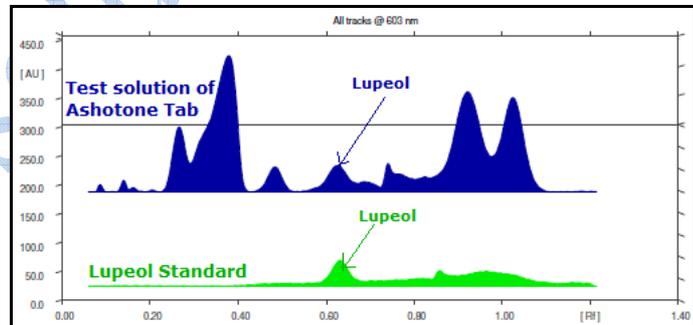
When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Diosgenin standard.



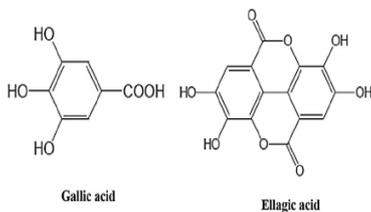
ii) Lupeol



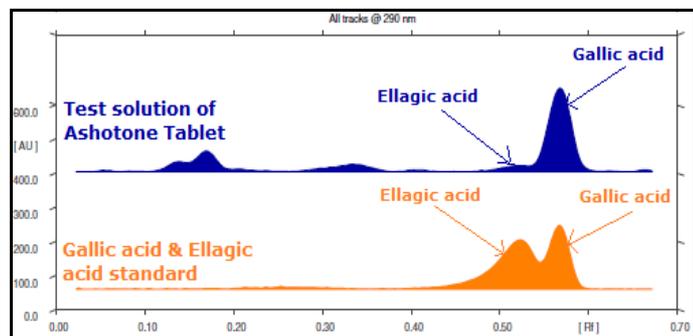
When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 600 nm corresponding with Lupeol standard.



iii) 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.



Acute Toxicity

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



Shree Dhootapapeshwar Standards

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

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