

SITOPALADI CHOORNA VATI

Monograph No. – 0300144 ver 3.0

Issue No: 03

IDate of Issue: 28/03/2017

Text Reference : Bhaishajya Ratnavali (Rajayakshma) 14/27-28

Amendment No : 01

Amendment Date : 18/12/2024

Shelf Life: 3 years

Description

Dull white coloured round biconvex coated tablets.

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 2.0 kg/cm²

Thickness

5.5 ± 0.5 mm

Diameter

12.0 - 12.5 mm

Average Weight

660 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 25 % w/w

Acid insoluble ash

Not more than 20 % w/w

Water soluble extractive

Not less than 35 % w/w

Alcohol soluble extractive

Not less than 20 % w/w

Thin Layer Chromatography

Solvent system

Toluene : Ethyl acetate
(7 : 3)

Details

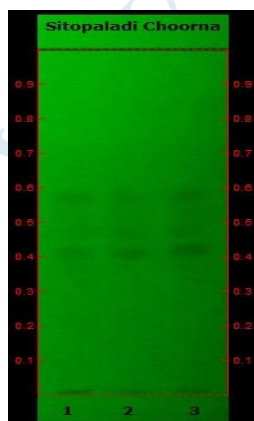
Solvent of Extraction – Methanol

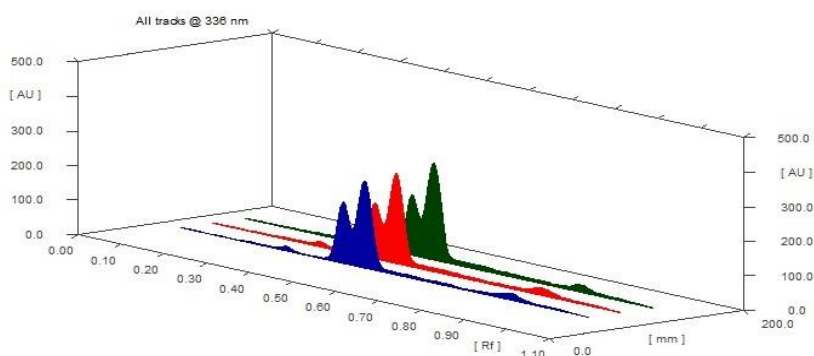
Solvent front – 90 mm

Total No. of Major spots – 4

Detection – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Gray	0.42
2	Light Gray	0.47
3	Light Gray	0.52
4	Gray	0.57



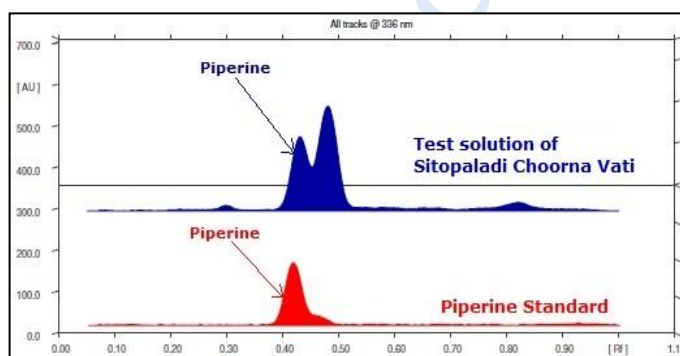
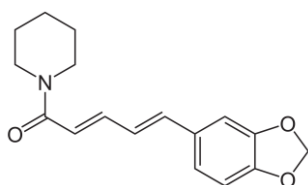


3D Peak Display of Sitopaladi Choorna Vati at 336 nm

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.



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