

SITOPALADI CHOORNA

Monograph No. – 030014 ver 3.0

Issue No: 03

Amendment No : 00

Date of Issue: 28/03/2017

Amendment Date : --

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

Shelf Life: 2 years

Description

Moderately fine to fine powder, Dull white colour, odour fragrant, taste sweet & pungent.

Loss on Drying at 105°

Not more than 5 % w/w

Ash

Not more than 27 % w/w

Acid Insoluble Ash

Not more than 27 % w/w

Water Soluble Extractive

Not less than 50 % w/w

Alcohol Soluble Extractive

Not less than 18 % w/w

Bulk Density

0.45 – 0.65

Thin Layer Chromatography Solvent system

Toluene : Ethyl acetate
(7 : 3)

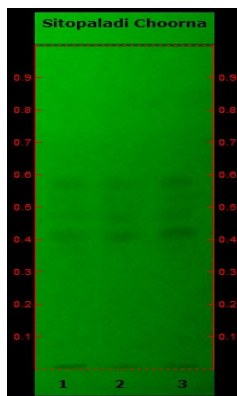
Details

Solvent of Extraction – Methanol

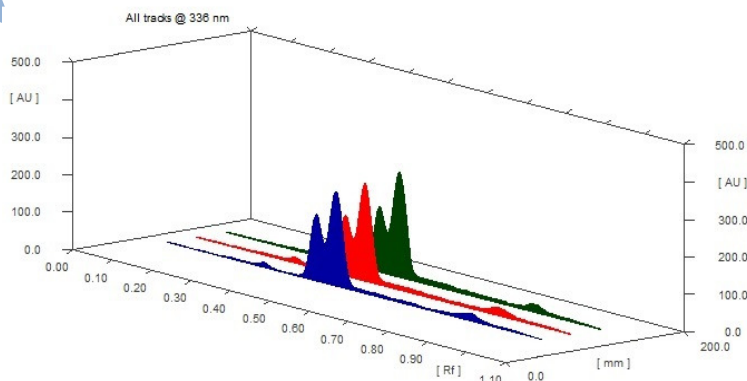
Solvent front – 90 mm

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 at 336 nm

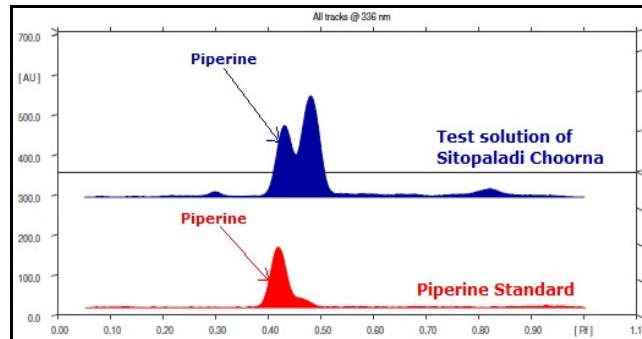
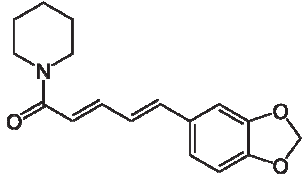
Confidential - photocopy prohibited

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

HPTLC Profile[†]

i) Piperine

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)	NMT 10 ppm
Mercury (Hg)	NMT 1 ppm
Arsenic (As)	NMT 3 ppm
Cadmium (Cd)	NMT 0.3 ppm
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

SITOPALADI CHOORNA VATI

Monograph No. – 0300144 ver 3.0

Issue No: 03

Amendment No : 00

IDate of Issue: 28/03/2017

Amendment Date : --

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

Shelf Life: 3 years

Description

Dull white coloured round biconvex coated tablets.

Loss on Drying at 105°

Not more than 7 % w/w

Hardness

Not less than 2.0 kg/cm²

Thickness

5.5 mm ± 0.5 mm

Diameter

12.0 - 12.5 mm

Disintegration Time

Not more than 60 min.

Average Weight

660 mg ± 5%

Uniformity of weight of 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 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)

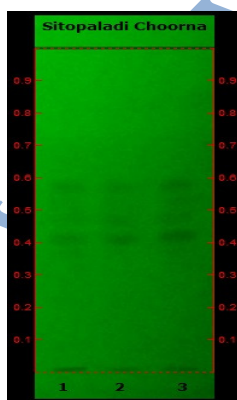
Details

Solvent of Extraction – Methanol

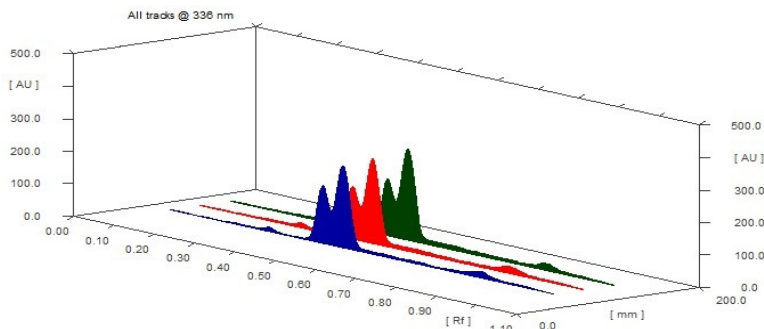
Solvent front – 90 mm

Total No. of Major spots – 4

Detection – Under UV at 254 nm



Major Spots	Colour	Approx. Rf.
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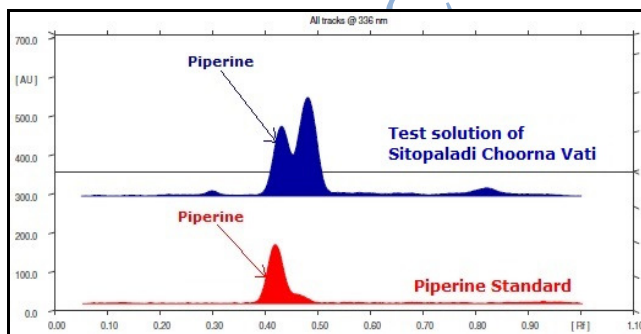
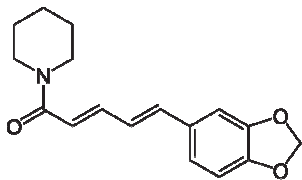


3D Peak Display of Sitopaladi Choorna Vati at 336 nm

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)	NMT 10 ppm
Mercury (Hg)	NMT 1 ppm
Arsenic (As)	NMT 3 ppm
Cadmium (Cd)	NMT 0.3 ppm

E. coli ⁺ Absent/g

P. aeruginosa ⁺ Absent/g

Salmonella sp. ⁺ Absent/g

Staphylococcus sp. ⁺ Absent/g

Total Microbial plate count (TPC) ⁺ NMT 10⁵ c.f.u./g

Total Yeast & Mould count⁺ NMT 10³ c.f.u./g

Pesticide Residue ⁺ (OC+OP) Complies as per API

Aflatoxins B1,B2,G1,G2 ⁺ Complies as per API