

SHANKHAVATI

Monograph No. – 0800184 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Bharat Bhaishajya Ratnakar 5/7555

Amendment No : 02

Amendment Date : 25/01/2025

Shelf Life: 5 years

Description

Dark gray to black colour, round biconvex coated tablets having SDL mark on one side.

Loss on Drying at 105°

Not more than 6 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 60 min.

Hardness

Not less than 2 kg/cm²

Thickness

5.0 ± 0.5 mm

Diameter

8.0 ± 0.5 mm

Average Weight

295 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 55 % w/w

Acid insoluble ash

Not more than 5 % w/w

Water soluble extractive

Not less than 30 % w/w

Alcohol soluble extractive

Not less than 18 % w/w

pH (1 % Aq. Solution)

7.5 – 10.5

Elemental Assay

Mercury (Hg)

3.0 – 5.0 mg/tablet

Sulphur (S)

3.0 – 5.0 mg/tablet

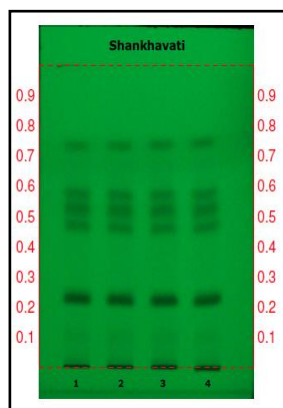
Calcium (Ca)

28.0 – 35.0 mg/tablet

Thin Layer Chromatography Solvent system

Chloroform : Hexane : Methanol
(8 : 1.8 : 0.2)

Details



Solvent of Extraction – Methanol

Solvent front – 90 mm

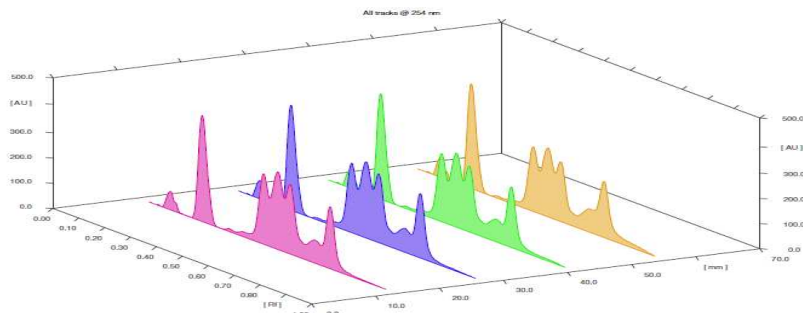
Total No. of Major spots – 5

Visualization – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Black	0.23
2	Gray	0.47
3	Gray	0.53
4	Gray	0.58
5	Gray	0.74

Confidential - photocopy prohibited

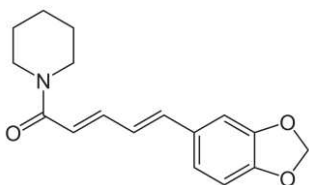
Note : † : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.



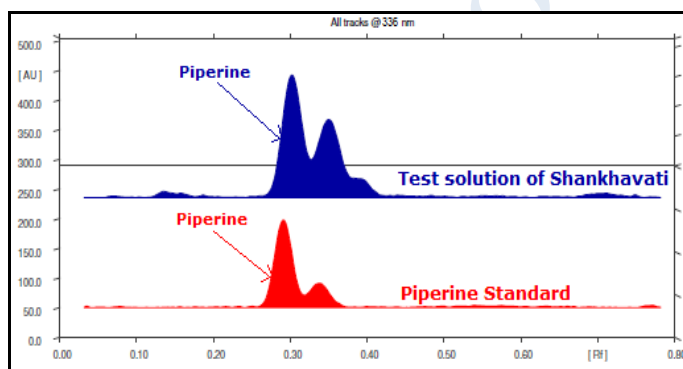
3D Peak Display of Shankhavati at 254 nm

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.



E. coli

Absent/g

P. aeruginosa

Absent/g

Salmonella sp.

Absent/g

Staphylococcus sp.

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