

EFIPLUS CAPSULE

Monograph No. – 070212 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

Pink coloured, "0" size, hard gelatin, filled capsules

Loss on Drying at 105°

Not more than 6 % w/w

Disintegration Time

Not more than 30 mins.

Average Weight

605 mg \pm 7.5%

Uniformity of weight on 20 Capsules

Not more than 2 capsules deviate by more than 7.5 % of the average fill weight and none by more than 15 %

Elemental Assay

Iron (Fe)

Not less than 50 mg/cap

Thin Layer Chromatography Mobile Phase

Toluene : Acetone
(7 : 3)

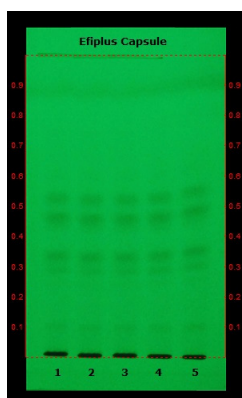
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

Total No. of Major spots – 5

Detection – Under UV at 254 nm

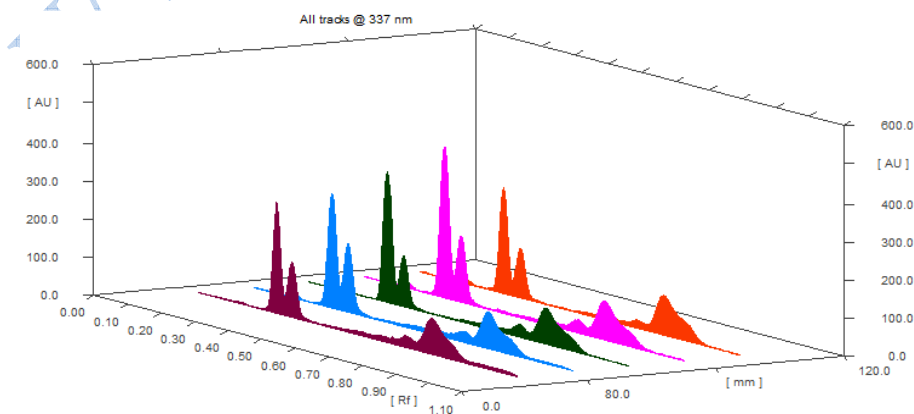


Major Spots

Colour

Approx. Rf.

1	Light Gray	0.10
2	Light Gray	0.29
3	Gray	0.34
4	Gray	0.46
5	Gray	0.53



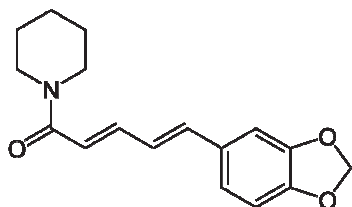
3D Peak Display of Eplus capsule at 337 nm

Confidential – photocopy prohibited

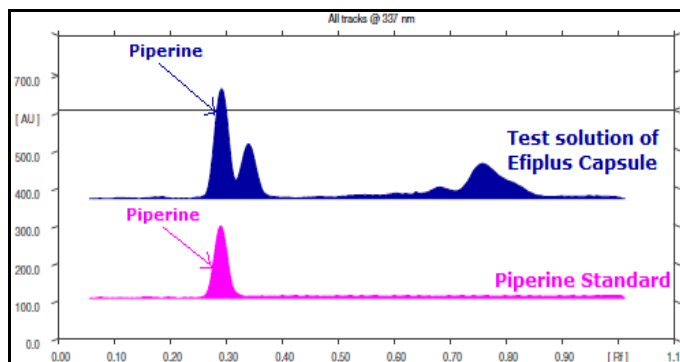
Note : [†] : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

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.



Acute Toxicity

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

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