

AFRODET PLUS CAPSULE

Monograph No. – 070200 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

Red-white coloured, "0" size hard gelatin capsules filled with Yellowish brown colour fine powder.



Loss on Drying at 105°

Not more than 5 % w/w

Disintegration Time

Not more than 30 mins.

Average Weight

525 mg ± 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

Zinc (Zn)

Not less than 10.0 mg/cap

Thin Layer Chromatography Mobile Phase

Chloroform : Methanol
(7 : 3)

Details

Solvent of Extraction – Methanol

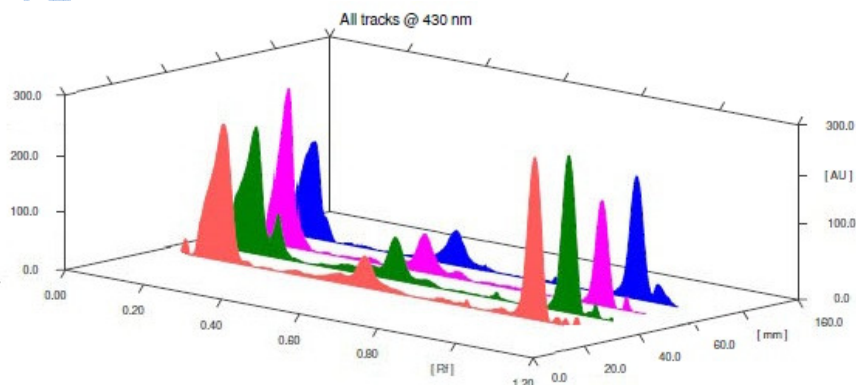
Solvent front – 90 mm

Total No. of Major spots – 5

Detection – After spraying Anisaldehyde H₂SO₄



Major Spots	Colour	Approx. Rf.
1	Gray	0.11
2	Light Yellow	0.46
3	Bluish Gray	0.84
4	Light Gray	0.91
5	Bluish Gray	0.97



3D Peak Display of Afrodet Plus Capsule at 430 nm

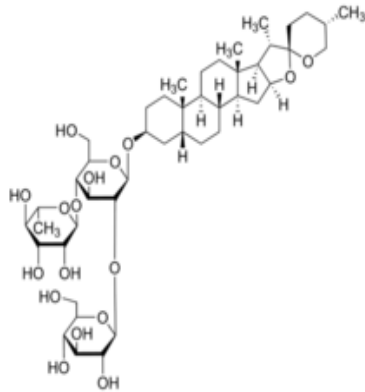
Confidential – photocopy prohibited

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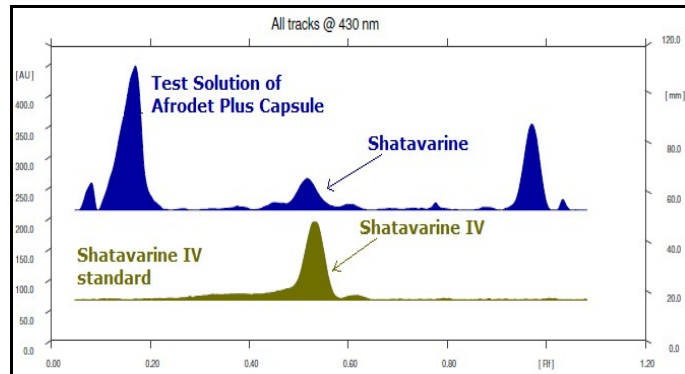
Note : † : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

HPTLC Profile

i) Shatavarin IV



When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 430 nm corresponding with Shatavarin IV 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