

AFROL PLUS WITH GOLD CAPSULE

Monograph No. – 070202 ver 3.0

Issue No: 03

Amendment No : 00

Date of Issue: 28/10/2016

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Text Reference : Ayurvedic Proprietary Medicine

Shelf Life: 5 years

Description

Scarlet red coloured, "0" size hard gelatin capsules filled with chocolate brown colour fine powder.



Loss on Drying at 105°

Not more than 5 % w/w

Disintegration Time

Not more than 30 mins.

Average Weight

740 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

Gold (Au)

1.8 – 2.2 mg/cap

Mercury (Hg)

18 – 24 mg/cap

Thin Layer Chromatography

Mobile Phase

Toluene : Ethyl acetate : Formic acid
(7 : 2 : 1)

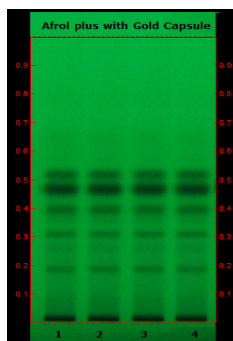
Details

Solvent of Extraction – 5% Methanolic HCl & Chloroform

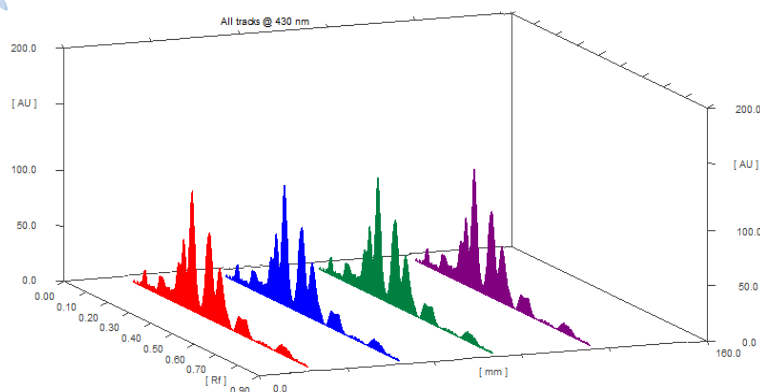
Solvent front – 90 mm

Total No. of Major spots – 6

Detection – Under UV at 254 nm



| Major Spots | Colour | Approx. Rf. |
|-------------|------------|-------------|
| 1 | Gray | 0.19 |
| 2 | Light Gray | 0.27 |
| 3 | Gray | 0.31 |
| 4 | Gray | 0.39 |
| 5 | Black | 0.47 |
| 6 | Dark Gray | 0.52 |



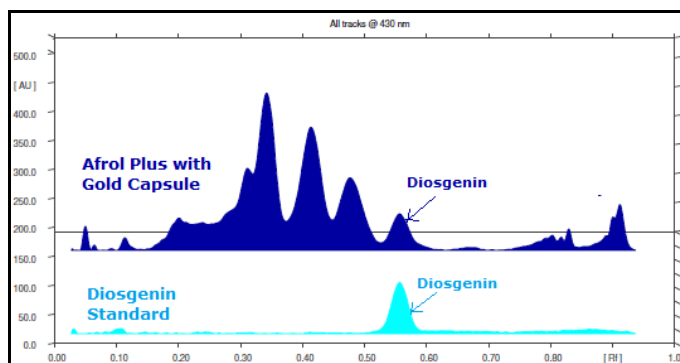
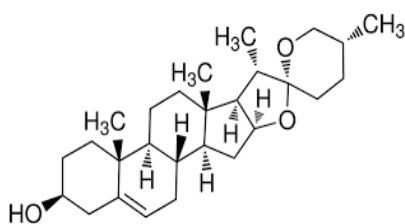
3D Peak Display of Afrol Plus with Gold Capsule at 430 nm

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HPTLC Profile

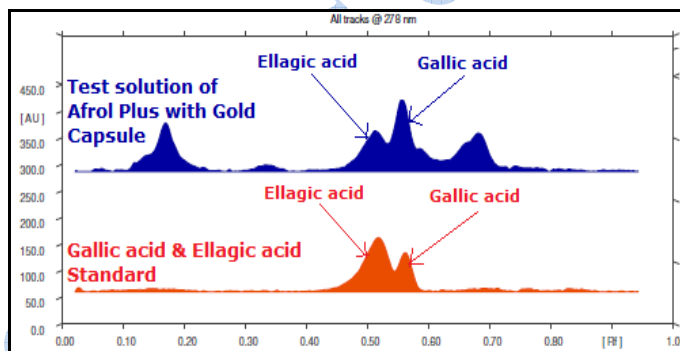
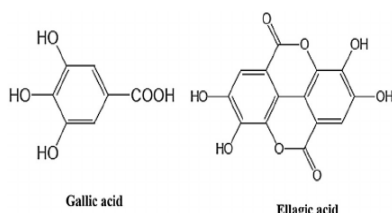
i) Diosgenin

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Diosgenin standard.



ii) Total Polyphenols (as Gallic acid & Ellagic acid)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid & 278 nm for Ellagic acid corresponding with Gallic acid & Ellagic acid 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