

DILAPSIN TABLET

Monograph No. – 070210 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

Orange coloured round biconvex film coated tablets.

Loss on Drying at 105°

Not more than 6 % w/w

Hardness

Not less than 2.5 kg/cm²

Thickness

5.5 ± 0.5 mm

Diameter

12 - 12.5 mm

Disintegration Time

Not more than 60 mins.

Average Weight

676 mg ± 5 %

Uniformity of weight on 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 32.5 % w/w

Acid insoluble ash

Not more than 10.5 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 4 % w/w

Elemental Assay

Iron (Fe)

Not less than 4.0 mg/tab

Thin Layer Chromatography

Mobile Phase

Toluene : Ethyl acetate : Formic acid
(4 : 4 : 2)

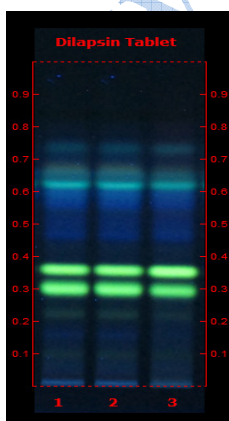
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

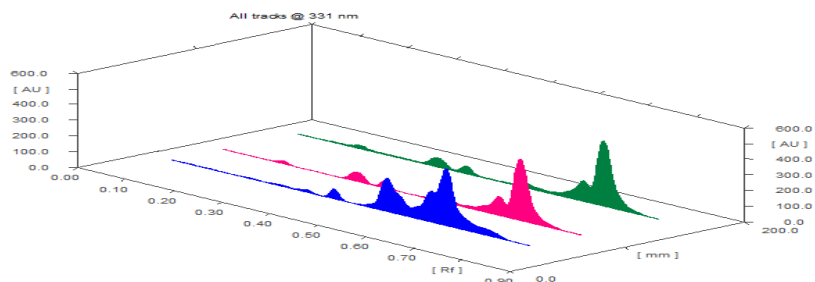
Total No. of Major spots – 9

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Light Yellow	0.09
2	Blue	0.15
3	Light Yellow	0.22
4	Fluorescent Green	0.30
5	Fluorescent Green	0.36
6	Blue	0.46
7	Fluorescent Blue	0.62
8	Light Blue	0.67
9	Light Blue	0.73



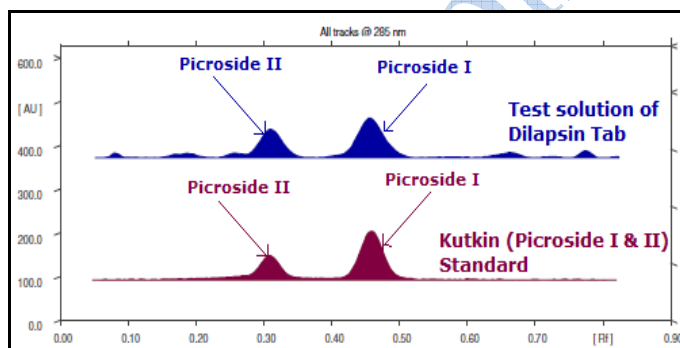
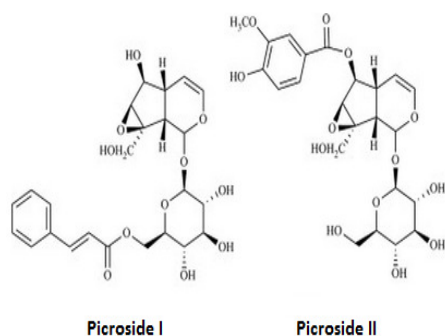


3D Peak Display of Dilapsin Tablet at 331 nm

HPTLC Profile

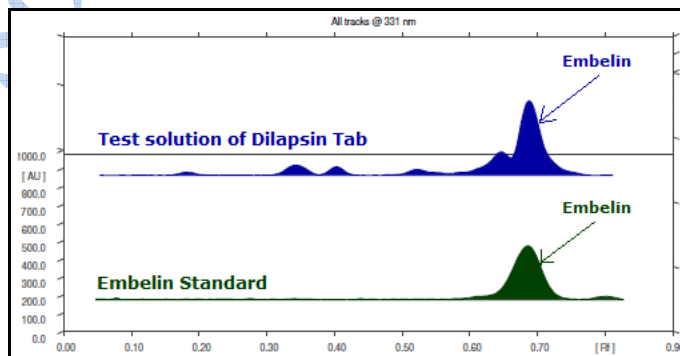
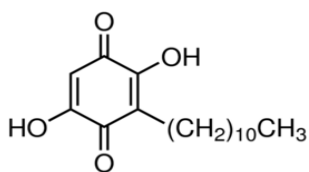
i) Kutkin (Picroside I & II)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 285 nm for Picroside I & 297 nm for Picroside II corresponding with Picroside I & Picroside II standard.



ii) Embelin

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 330 nm corresponding with Embelin standard.



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