

## DILAPSIN TABLET

Monograph No. – 070210 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 01

Amendment Date : 03/09/2024

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/cm<sup>2</sup>

### 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 )

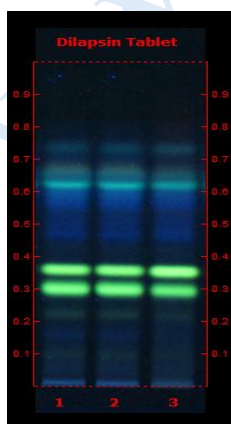
### Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

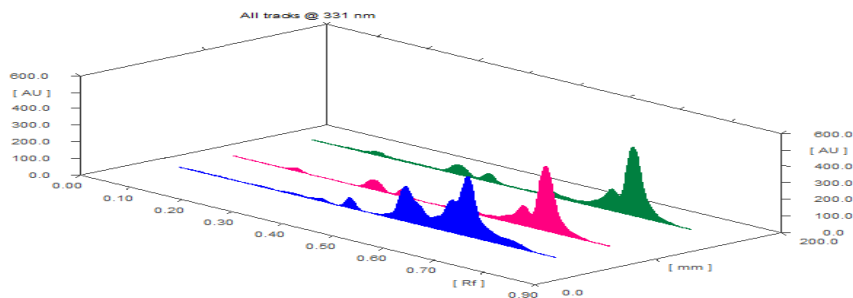
Total No. of Major spots – 9

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



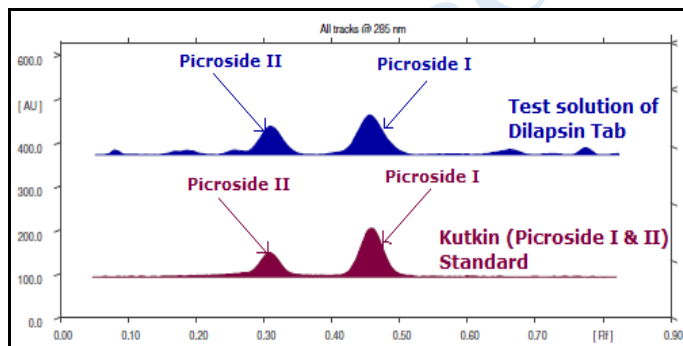
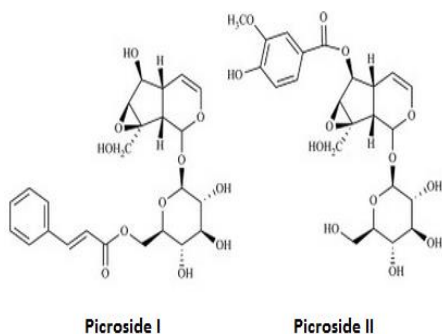


3D Peak Display of Dilapsin Tablet at 331 nm

## HPTLC Profile<sup>+</sup>

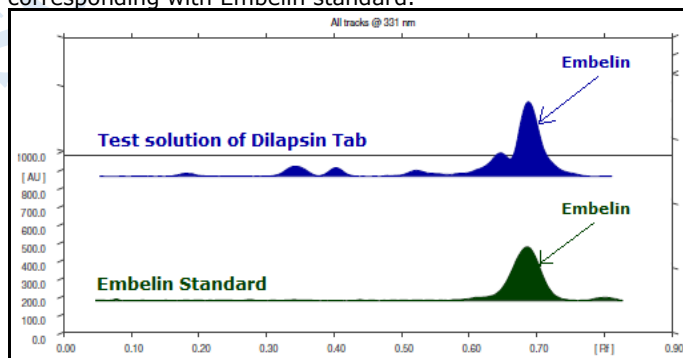
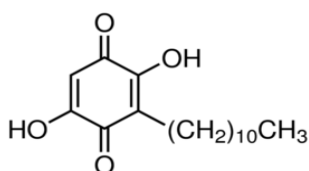
### i) Kutkin (Picroside I & II)

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 331 nm corresponding with Embelin standard.



<b><i>E. coli</i></b>	Absent/g
<b><i>P. aeruginosa</i></b>	Absent/g
<b><i>Salmonella sp.</i></b>	Absent/g
<b><i>Staphylococcus sp.</i></b>	Absent/g
<b>Total Microbial plate count (TPC)</b>	NMT 10 <sup>5</sup> c.f.u./g
<b>Total Yeast &amp; Mould count (TYMC)</b>	NMT 10 <sup>3</sup> c.f.u./g
<b>Pesticide Residue<sup>+</sup> (OC+OP)</b>	Complies as per API
<b>Aflatoxins B1,B2,G1,G2<sup>+</sup></b>	Complies as per API