

## LUMITAL TABLET

Monograph No. – 070218 ver 3.0

Issue No: 03

Amendment No : 00

Date of Issue: 28/10/2016

Amendment Date : --

Text Reference : Ayurvedic Proprietary Medicine

Shelf Life: 5 years

### Description

Light grey coloured round biconvex film 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 41 % w/w

### Acid insoluble ash

Not more than 6 % w/w

### Water soluble extractive

Not less than 20 % w/w

### Alcohol soluble extractive

Not less than 5 % w/w

### Elemental Assay

#### Zinc (Zn)

6.0 – 9.0 mg/tab

#### Calcium (Ca)

Not less than 8.0 mg/tab

#### Sulphur (S)

Not less than 13.0 mg/tab

### Thin Layer Chromatography

#### Mobile Phase

Toluene : Acetone : Formic acid  
( 18 : 2 : 0.9 )

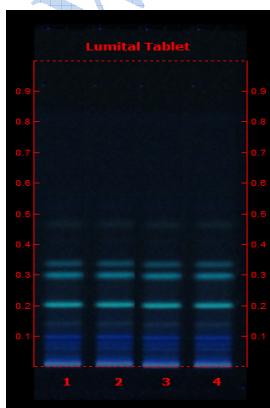
### Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

Total No. of Major spots – 8

Detection – Under UV at 366 nm

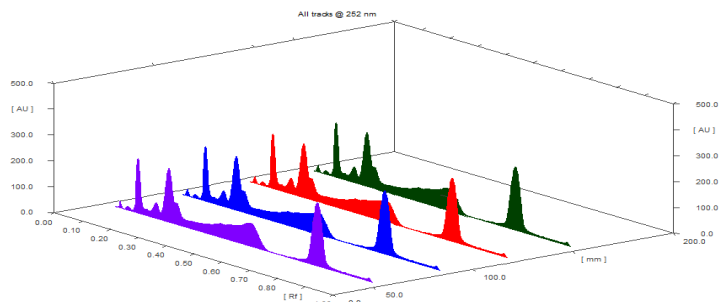


Major Spots	Colour	Approx. Rf.
1	Blue	0.06
2	Blue	0.08
3	Blue	0.10
4	Light Blue	0.14
5	Sky Blue	0.20
6	Sky Blue	0.29
7	Sky Blue	0.35
8	Light Blue	0.47

Confidential – photocopy prohibited

24

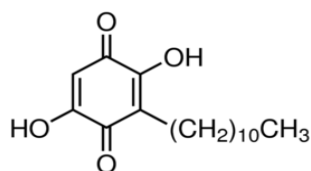
Note : † : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.



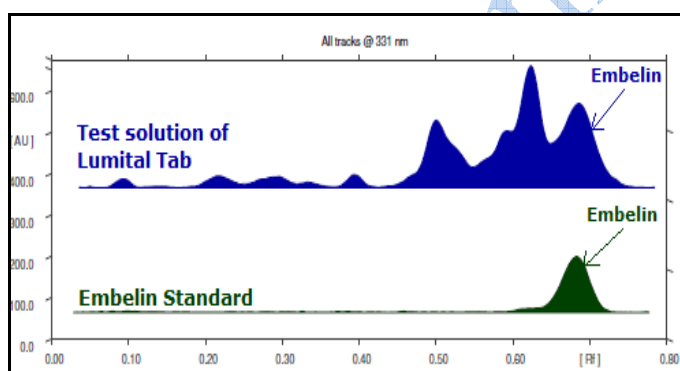
**3D Peak Display of Lumital Tablet at 252 nm**

## HPTLC Profile

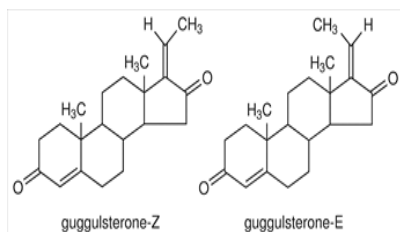
### i) Embelin



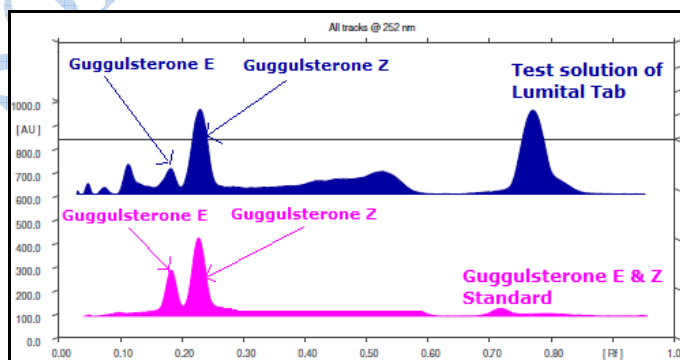
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 330 nm corresponding with Embelin standard.



### ii) Guggulsterone (E & Z)



When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 252 nm corresponding with Guggulsterone (E & Z) standard.



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