

ENTOSTAL TABLET

Monograph No. – 070214 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

Light 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 36 % w/w

Acid insoluble ash

Not more than 5 % w/w

Water soluble extractive

Not less than 22 % w/w

Alcohol soluble extractive

Not less than 4 % w/w

Elemental Assay

Mercury (Hg)

3.0 – 5.0 mg/tab

Sulphur (S)

Not less than 4.0 mg/tab

Thin Layer Chromatography Mobile Phase

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

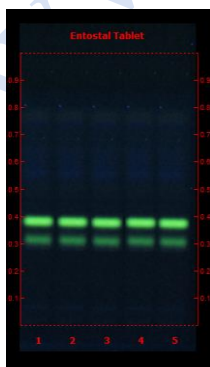
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

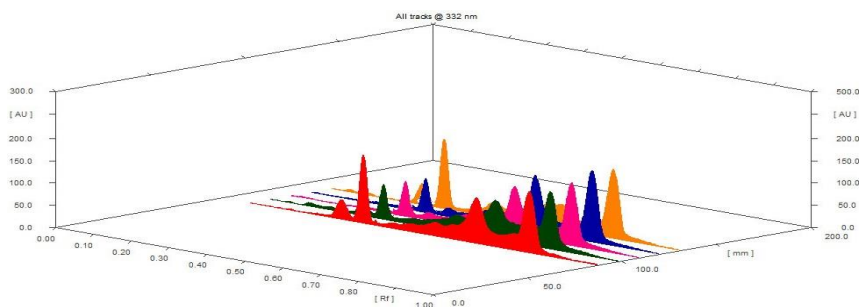
Total No. of Major spots – 5

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Light Blue	0.06
2	Fluorescent Green	0.31
3	Fluorescent Green	0.38
4	Blue	0.55
5	Light Blue	0.76

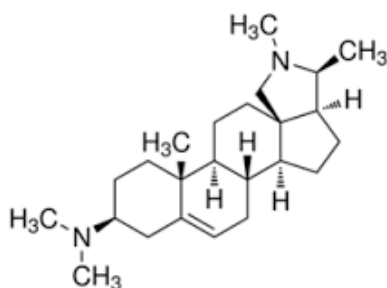




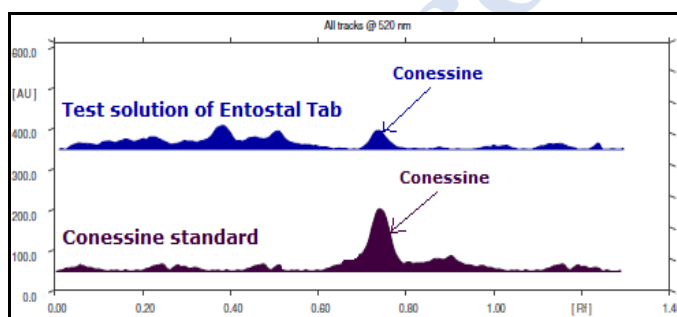
3D Peak Display of Entostal Tablet at 332 nm

HPTLC Profile[†]

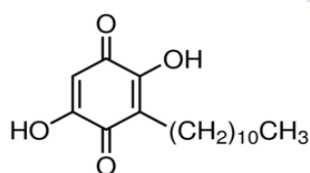
i) Conessine



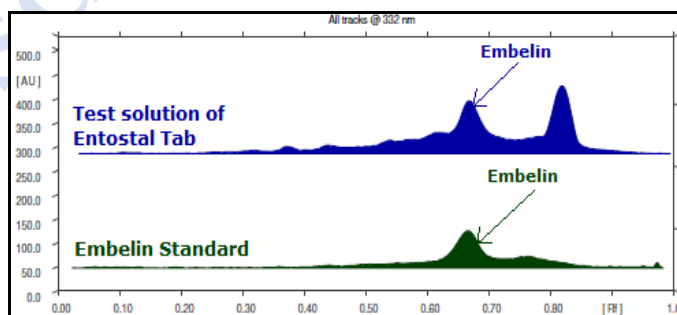
When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 520 nm corresponding with Conessine standard.



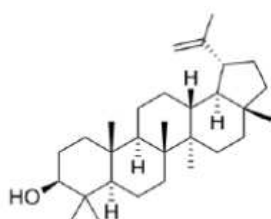
ii) Embelin



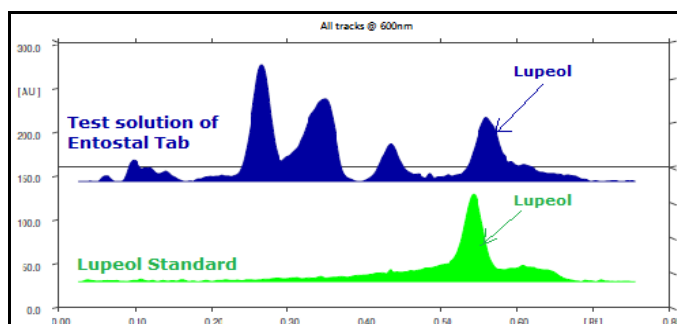
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 332 nm corresponding with Embelin standard.



iii) Lupeol



When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 600 nm corresponding with Lupeol standard.



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

Acute Toxicity	Nontoxic 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 10 ⁵ c.f.u./g
Total Yeast & Mould count (TYMC)	NMT 10 ³ c.f.u./g
Pesticide Residue [†] (OC+OP)	Complies as per API
Aflatoxins B1,B2,G1,G2 [†]	Complies as per API