

MYOSTAAL TABLET

Monograph No. – 070226 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

Yellow 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

12.0 – 12.50 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 35 % w/w

Acid insoluble ash

Not more than 9 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 6 % w/w

Elemental Assay

Iron (Fe)

3.5 – 6.0 mg/tab

Zinc (Zn)

3.5 – 5.0 mg/tab

Mercury (Hg)

2.2 – 3.5 mg/tab

Lead (Pb)

2.0 – 3.0 mg/tab

Thin Layer Chromatography

Mobile Phase

Toluene : Acetone
(9 : 1)

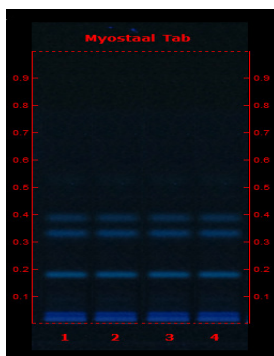
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

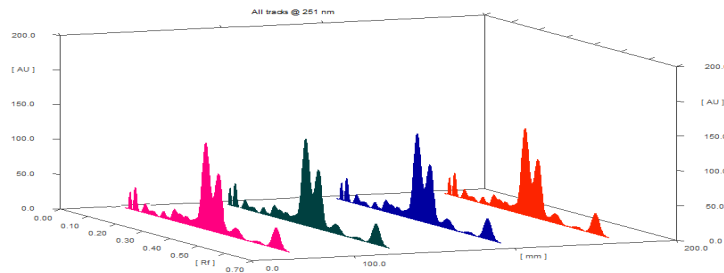
Total No. of Major spots – 4

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Blue	0.03
2	Light Blue	0.17
3	Light Blue	0.32
4	Light Blue	0.38



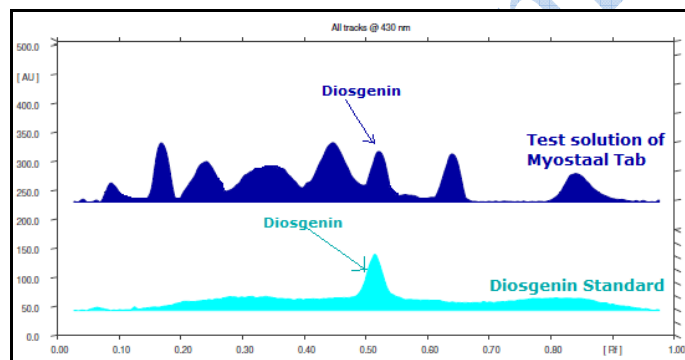
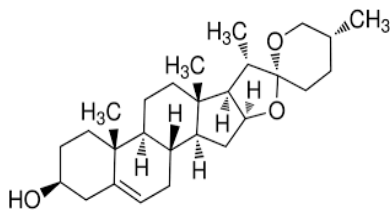


3D Peak Display of Myostaal Tablet at 251 nm

HPTLC Profile

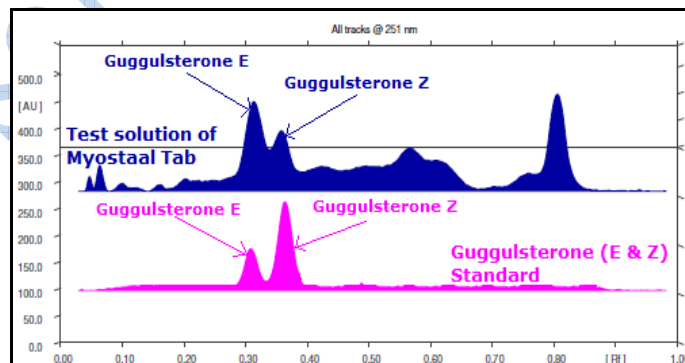
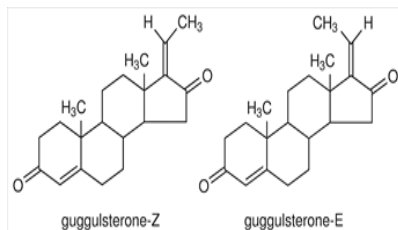
i) Diosgenin

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) Guggulsterone (E & Z)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 251 nm corresponding with Guggulsterone (E & Z) 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

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