

MYOSTAAL TABLET

Monograph No. – 070226 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

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)

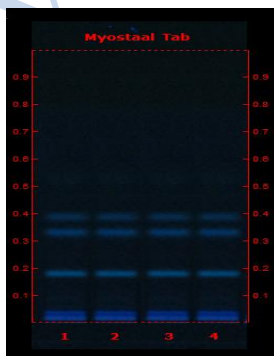
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

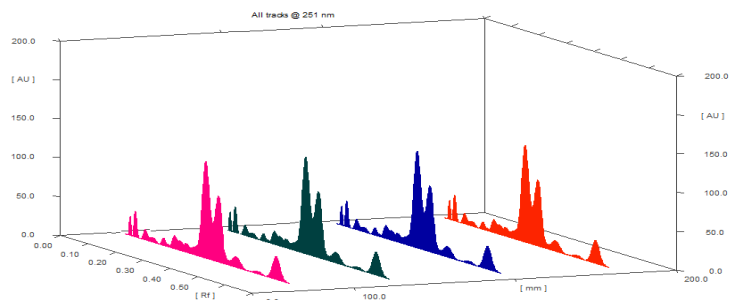
Total No. of Major spots – 4

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



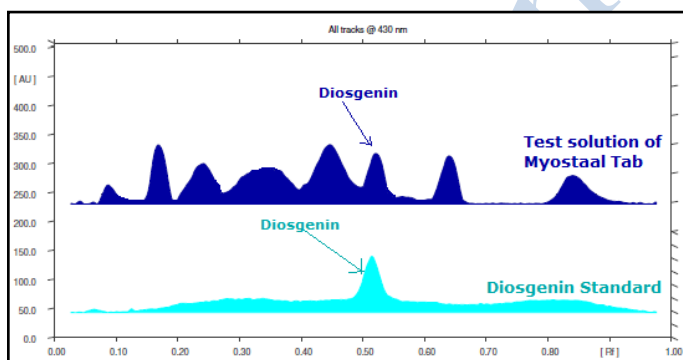
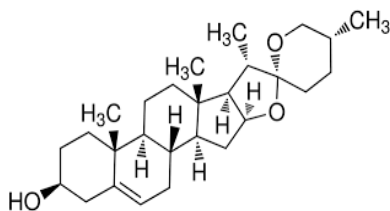


3D Peak Display of Myostaal Tablet at 251 nm

HPTLC Profile[†]

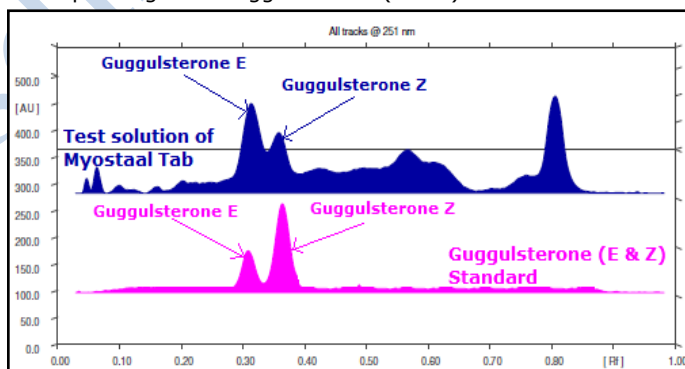
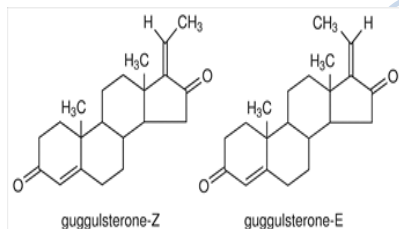
i) Diosgenin

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

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 10⁵ c.f.u./g

Total Yeast & Mould count (TYMC)

NMT 10³ c.f.u./g

Pesticide Residue[†] (OC+OP)

Complies as per API

Aflatoxins B1,B2,G1,G2[†]

Complies as per API