

MYOSTAAL FORTE TABLET

Monograph No. – 070250 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

Red 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

6.0 ± 0.5 mm

Diameter

12.0 - 12.5 mm

Disintegration Time

Not more than 60 min.

Average Weight

686 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 31 % w/w

Acid insoluble ash

Not more than 16 % w/w

Water soluble extractive

Not less than 17 % w/w

Alcohol soluble extractive

Not less than 16 % w/w

Thin Layer Chromatography

Mobile Phase

Toluene : Acetone
(9 : 1)

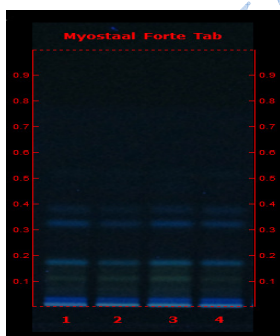
Details

Solvent of Extraction – Methanol

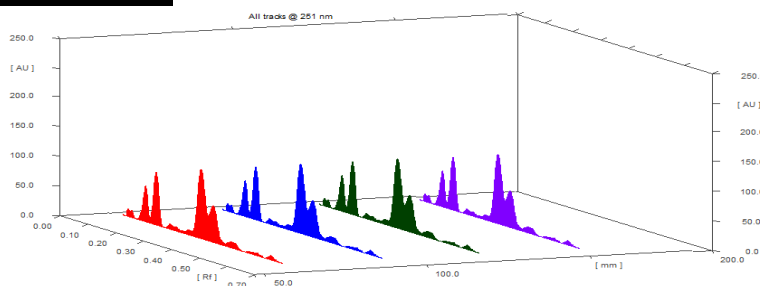
Solvent front – 90 mm

Total No. of Major spots – 5

Detection – Under UV at 366 nm



| Major Spots | Colour | Approx. Rf. |
|-------------|-------------|-------------|
| 1 | Blue | 0.03 |
| 2 | Light Green | 0.11 |
| 3 | Light Blue | 0.17 |
| 4 | Light Blue | 0.32 |
| 5 | Light Blue | 0.38 |



3D Peak Display of Myostaal Forte Tablet at 251 nm

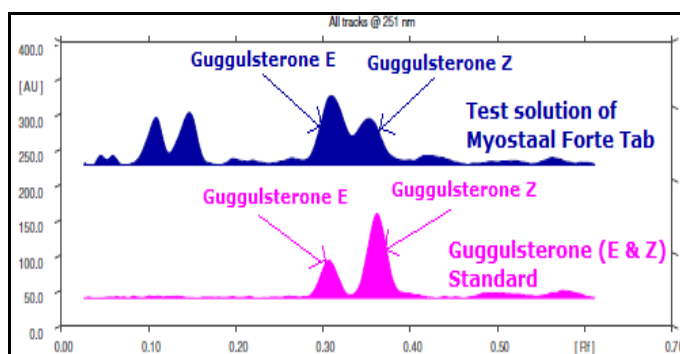
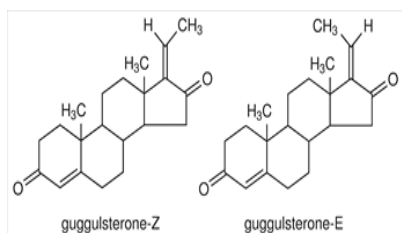
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Note : † : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

HPTLC Profile

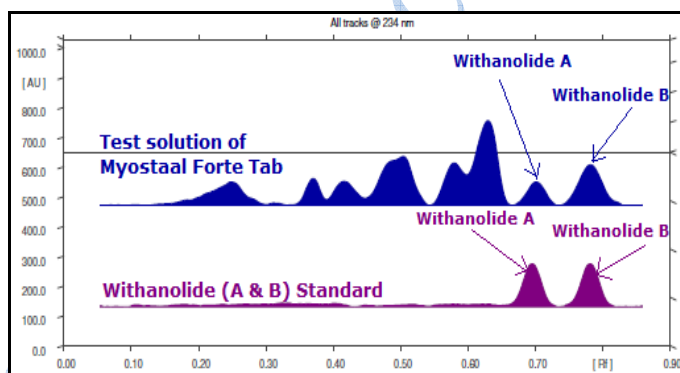
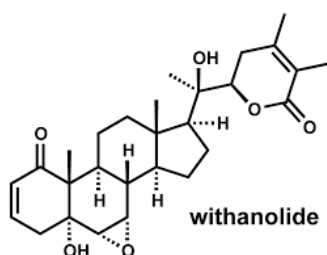
i) Guggulsterone (E & Z)

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.



ii) Withanolide (A & B)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 234 nm corresponding with Withanolide (A & B) standard.



Heavy metal

| | |
|---|------------------------------|
| Lead (Pb) | NMT 10 ppm |
| Mercury (Hg) | NMT 1 ppm |
| Arsenic (As) | NMT 3 ppm |
| Cadmium (Cd) | NMT 0.3 ppm |
| 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⁺ | NMT 10 ³ c.f.u./g |
| Pesticide Residue ⁺ (OC+OP) | Complies as per API |
| Aflatoxins B1,B2,G1,G2 ⁺ | Complies as per API |