

MENOCRAMP TABLET

Monograph No. – 070221 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

Green 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 30 % w/w

Acid insoluble ash

Not more than 5 % w/w

Water soluble extractive

Not less than 25 % w/w

Alcohol soluble extractive

Not less than 5 % w/w

Thin Layer Chromatography

Mobile Phase

Chloroform : Methanol
(9 : 1)

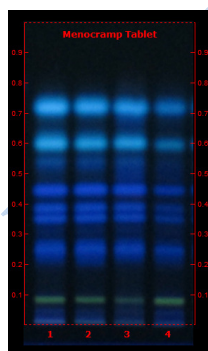
Details

Solvent of Extraction – Methanol

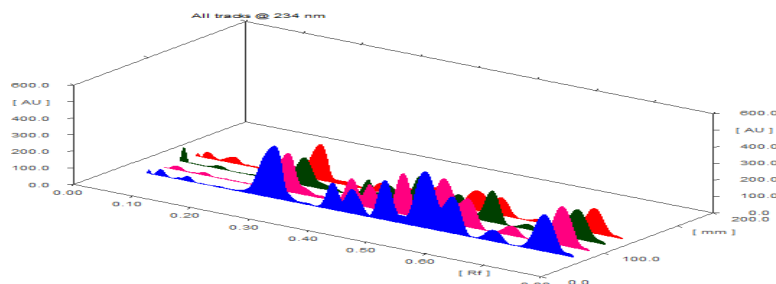
Solvent front – 90 mm

Total No. of Major spots – 8

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Green	0.08
2	Blue	0.25
3	Blue	0.35
4	Blue	0.39
5	Blue	0.44
6	Light Blue	0.53
7	Light Blue	0.60
8	Light Blue	0.72



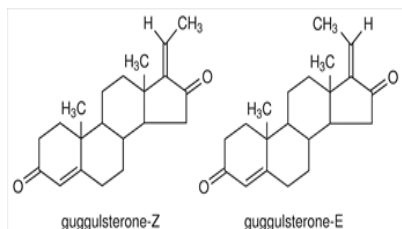
3D Peak Display of Menocramp Tablet at 234 nm

Confidential – photocopy prohibited

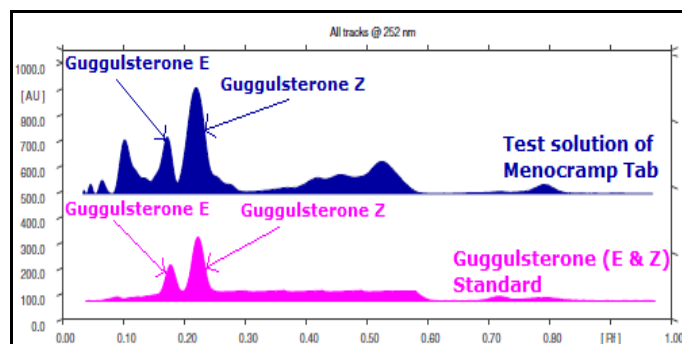
Note : † : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

HPTLC Profile

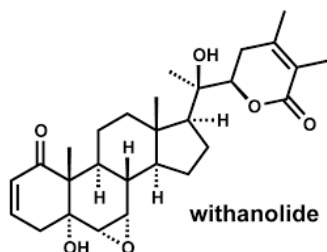
i) Guggulsterone (E & Z)



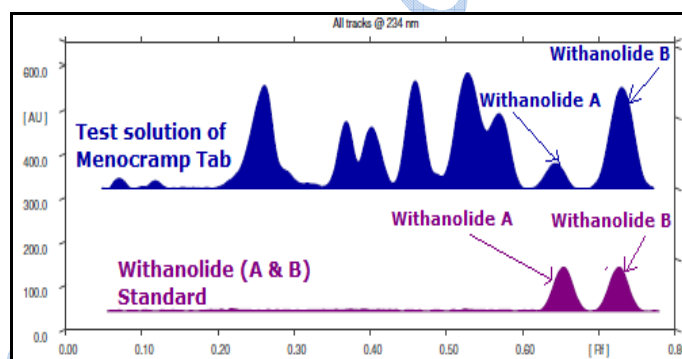
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 251 nm corresponding with Guggulsterone (E & Z) standard.



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