

## GOKSHURA TABLET

Monograph No. – 2700184 ver 3.0

Issue No: 03

Date of Issue: 13/10/2022

Text Reference : API, Part I, Volume I, Monograph No. 26

Amendment No : 00

Amendment Date : --

Shelf Life: 3 years

### Description

Light brown to brown colour, caplet shape coated tablet having SDL mark on one side.

### Loss on Drying at 105°

Not more than 7.5 % w/w

### Friability

Not more than 1 % w/w

### Disintegration Time

Not more than 60 min.

### Hardness

Not less than 2 kg/cm<sup>2</sup>

### Thickness

5.5 ± 0.5 mm

### Length

17.5 ± 0.5 mm

### Average Weight

670 mg ± 5 %

### Uniformity of weight

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 22 % w/w

### Acid insoluble ash

Not more than 3 % w/w

### Water soluble extractive

Not less than 10 % w/w

### Alcohol soluble extractive

Not less than 6 % w/w

### pH (1% aq. solution)

4.0 - 7.0

### Thin Layer Chromatography Mobile Phase

Toluene : Ethyl Acetate  
( 8 : 1 )

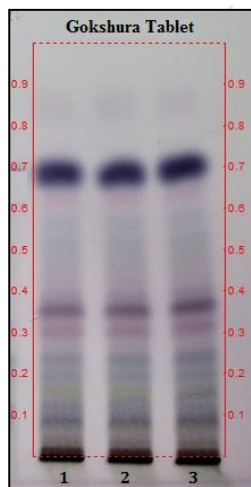
### Details

Solvent of Extraction – 5% Methanolic HCL + D/W + Chloroform

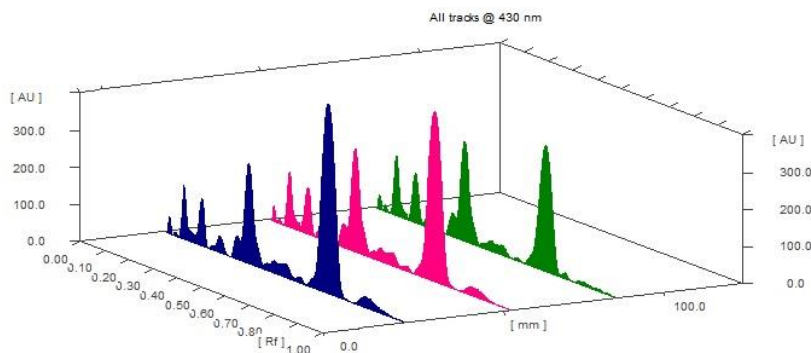
Distance traveled by solvent front – 90 mm

Total No. of Major spots – 8

Detection – After spray with Anisaldehyde sulfuric acid reagent



Major Spots	Color	Approx. Rf.
1	Gray	0.09
2	Light Violet	0.12
3	Greenish Yellow	0.17
4	Light Blue	0.19
5	Light Blue	0.23
6	Pink	0.30
7	Purple	0.35
8	Violet	0.69

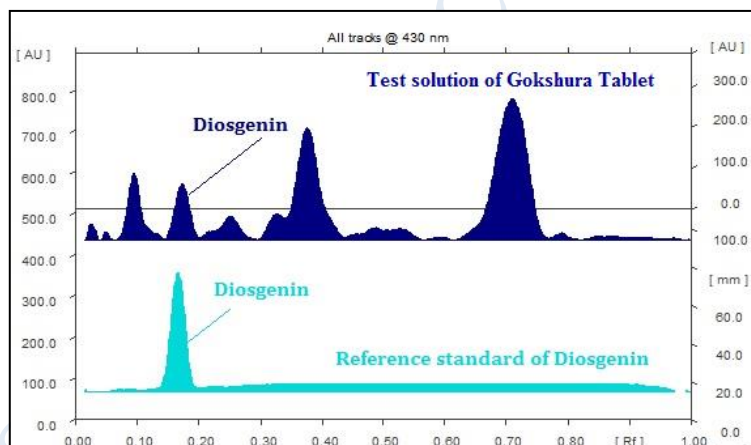
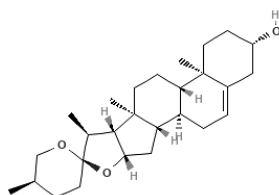


**3D Peak Display of Gokshura Tablet at 430 nm**

## HPTLC Profile<sup>+</sup>

### 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.



## Heavy metal

<b>Lead (Pb)</b>	NMT 10 ppm
<b>Mercury (Hg)</b>	NMT 1 ppm
<b>Arsenic (As)</b>	NMT 3 ppm
<b>Cadmium (Cd)</b>	NMT 0.3 ppm
<b>E. coli</b>	Absent/g
<b>P. aeruginosa</b>	Absent/g
<b>Salmonella sp.</b>	Absent/g
<b>Staphylococcus sp.</b>	Absent/g
<b>Total Microbial plate count (TPC)</b>	NMT 10 <sup>5</sup> c.f.u./g
<b>Total Yeast &amp; Mould count (TYMC)</b>	NMT 10 <sup>3</sup> c.f.u./g
<b>Pesticide Residue<sup>+</sup> (OC+OP)</b>	Complies as per API
<b>Aflatoxins B1,B2,G1,G2<sup>+</sup></b>	Complies as per API