

## SHATAVARI TABLETS

### Monograph No. 2103784 ver 3.0

Issue No: 03

Date of Issue: 05/04/2021

Text Reference : API, Part I, Volume IV, Monograph no. 50

Amendment No : 01

Amendment Date : 11/04/2022

Shelf Life: 3 years

#### Description

Cream to light brown colour caplet shape coated tablet having SDL mark on one side

#### Loss on Drying at 105°

Not more than 7 % 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 of 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.

#### pH

5.0 – 7.0

#### Ash

Not more than 7 % w/w

#### Acid insoluble ash

Not more than 2 % w/w

#### Water soluble extractive

Not less than 45 % w/w

#### Alcohol soluble extractive

Not less than 36 % w/w

#### Thin Layer Chromatography Solvent system

Chloroform : Methanol  
( 7 : 3 )

#### Details

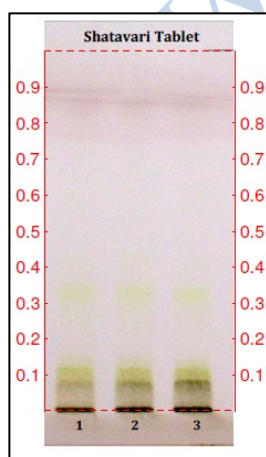
Solvent of Extraction – Methanol

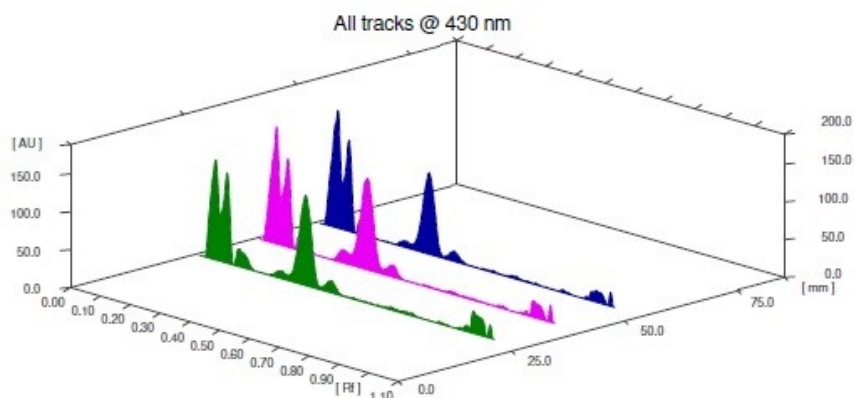
Solvent front – 90 mm

Total No. of Major spots – 3

Detection – After spray with Anisaldehyde Sulfuric acid

Major Spots	Colour	Approx. Rf.
1	Brown	0.07
2	Yellow	0.11
3	Yellow	0.33



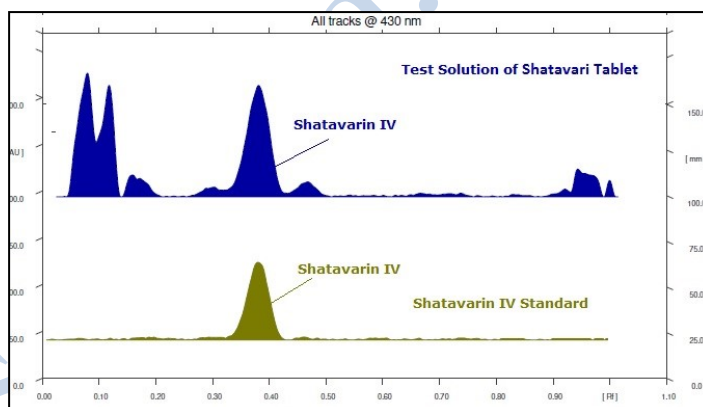
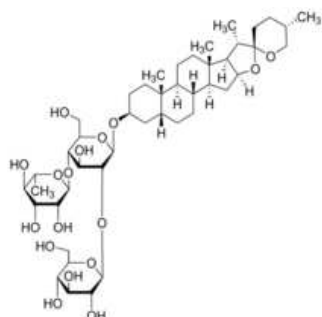


**3D Peak Display of Shatavari Tablet at 430 nm**

## HPTLC Profile<sup>†</sup>

### i) Shatavarin IV

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Shatavarin IV 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

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