

ASHVAGANDHA TABLETS

Monograph No. – 2700104 ver 3.0

Issue No: 03

Amendment No : 01

Date of Issue: 05/11/2020

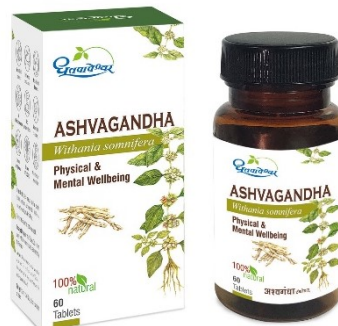
Amendment Date : 11/04/2022

Text Reference: API Part I, Volume I, Monograph No. 10

Shelf Life: 3 years

Description

Yellowish brown to light brown color caplet shape coated tablets 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/cm²

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

4.5 – 6.5

Ash

Not more than 10 % w/w

Acid insoluble ash

Not more than 2 % w/w

Water soluble extractive

Not less than 30 % w/w

Alcohol soluble extractive

Not less than 15 % w/w

Thin Layer Chromatography Solvent system

Chloroform : Methanol
(9 : 1)

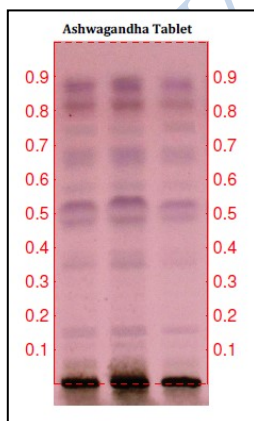
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

Total No. of Major spots – 9

Detection – After spraying with Anisaldehyde H₂SO₄

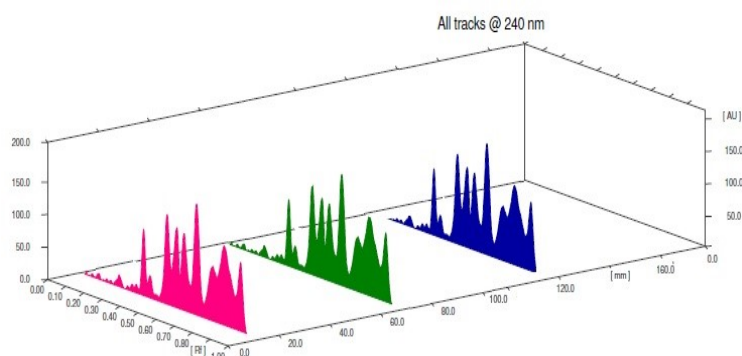


Major Spots	Colour	Approx. Rf.
1	Light Purple	0.16
2	Purple	0.35
3	Purple	0.38
4	Violet	0.48
5	Violet	0.53
6	Light Purple	0.58
7	Violet	0.67
8	Violet	0.81
9	Violet	0.89

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

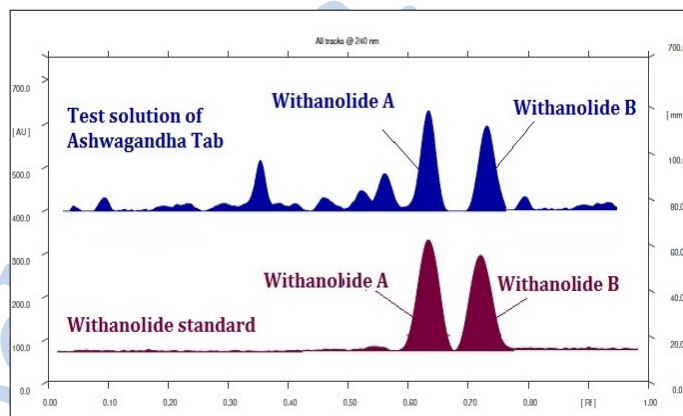
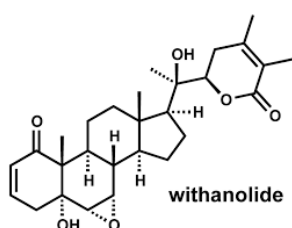


3D Peak Display of Ashvagandha Tablet at 240 nm

HPTLC Profile[†]

i) Withanolide A & B

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 240 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 (TYMC)	NMT 10 ³ c.f.u./g
Pesticide Residue[†] (OC+OP)	Complies as per API
Aflatoxins B1,B2,G1,G2[†]	Complies as per API