

BRAHMI TABLETS

Monograph No. 2100614 ver 3.0

Issue No: 03

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Text Reference : API, Part I, Volume II, Monograph no. 11

Amendment No : 01

Amendment Date : 11/04/2022

Shelf Life: 3 years

Description

Light gray to Gray 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/cm²

Thickness

5.5 ± 0.5 mm

Length

18.0 ± 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

5.5 – 7.5

Ash

Not more than 22 % w/w

Acid insoluble ash

Not more than 12 % w/w

Water soluble extractive

Not less than 20 % w/w

Alcohol soluble extractive

Not less than 14 % w/w

Thin Layer Chromatography Solvent system

Ethyl acetate : Methanol : Toluene : Water
(4 : 1 : 1 : 0.5)

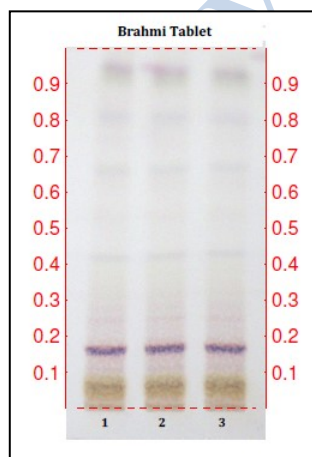
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

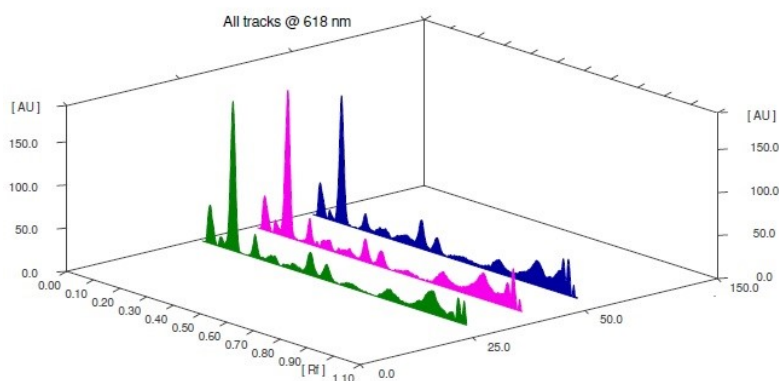
Total No. of Major spots – 7

Detection – Detection after Anisaldehyde sulfuric acid reagent



Major Spots	Colour	Approx. Rf.
1	Brown	0.05
2	Purple	0.16
3	Light Brown	0.24
4	Light Purple	0.43
5	Light Purple	0.67
6	Light Purple	0.80
7	Purple	0.90



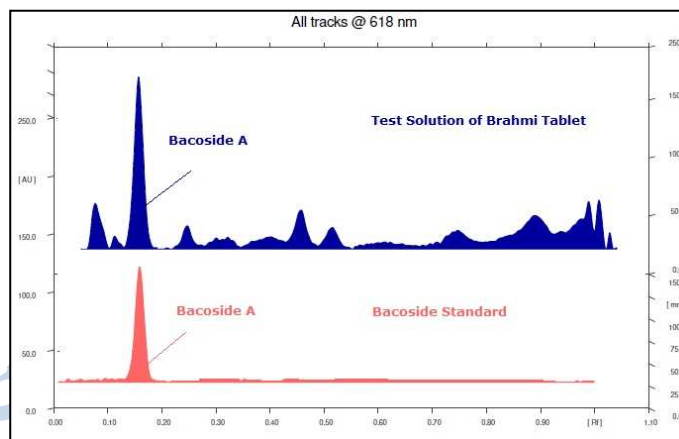
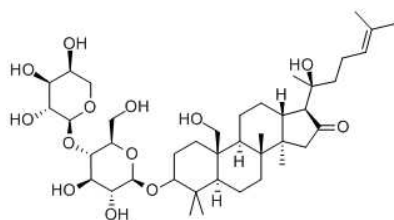


3D Peak Display of Brahmi Tablet at 618 nm

HPTLC Profile[†]

i) Bacoside

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 618 nm corresponding with Bacoside 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 10⁵ c.f.u./g

Total Yeast & Mould Count (TYMC) NMT 10³ c.f.u./g

Pesticide Residue[†] (OC+OP) Complies as per API

Aflatoxins B1,B2,G1,G2[†] Complies as per API

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