

AYUSH KWATH DISPERSIBLE TABLETS

Monograph No. – 0301494 ver 3.0

Issue No: 01

Date of Issue: 15/06/2020

Amendment No : 00

Amendment Date : --

Shelf Life: 3 years

Description

Light brown to brown colour, round shape dispersible tablets having SDL mark on one side.



Loss on Drying at 105°

Not more than 6 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 3 min.

Hardness

Not less than 1.5 kg/cm²

Average weight

643 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.

Thin Layer Chromatography Solvent system

Toluene : Ethyl acetate
(8 : 3)

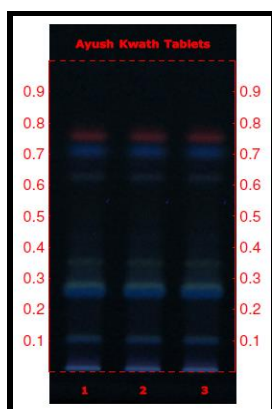
Details

Solvent of Extraction – Methanol

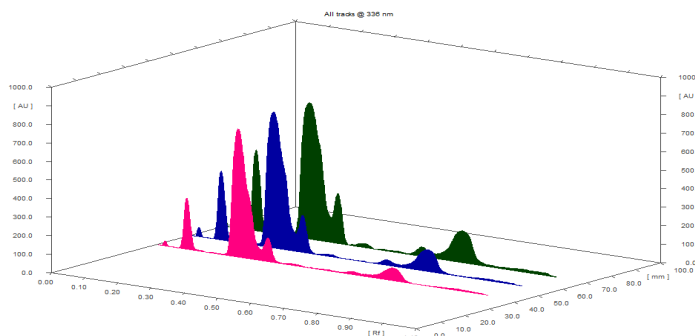
Solvent front – 90 mm

Total No. of Major spots – 7

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Blue	0.10
2	Blue	0.25
3	Greenish yellow	0.28
4	Greenish yellow	0.35
5	Gray	0.62
6	Blue	0.70
7	Red	0.75



3D Peak Display of Ayush Kwath at 336 nm

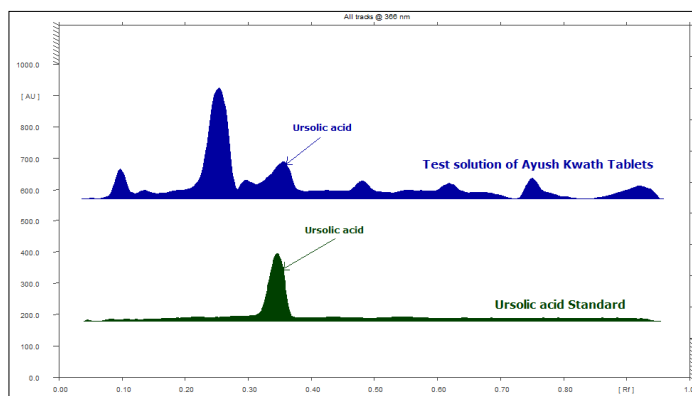
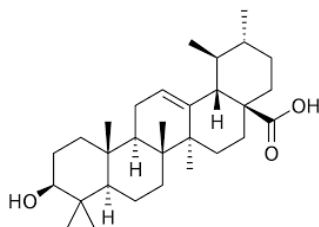
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Note : † : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

HPTLC Profile[†]

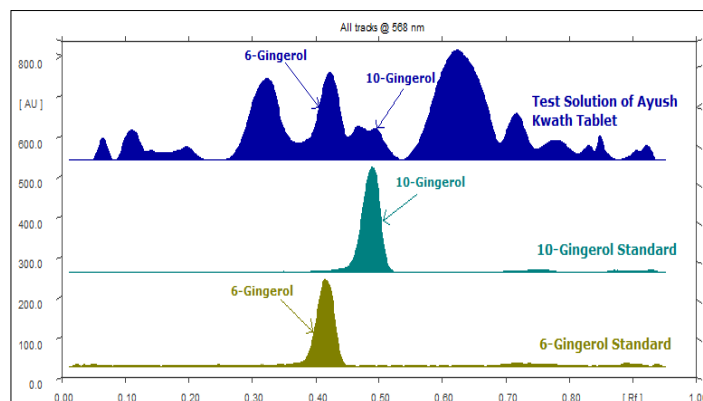
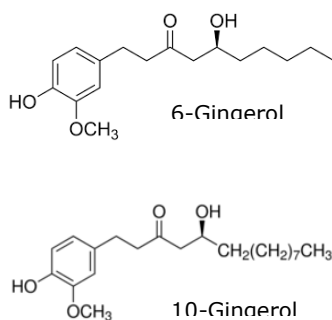
i) Ursolic acid

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 366 nm corresponding with Ursolic acid standard.



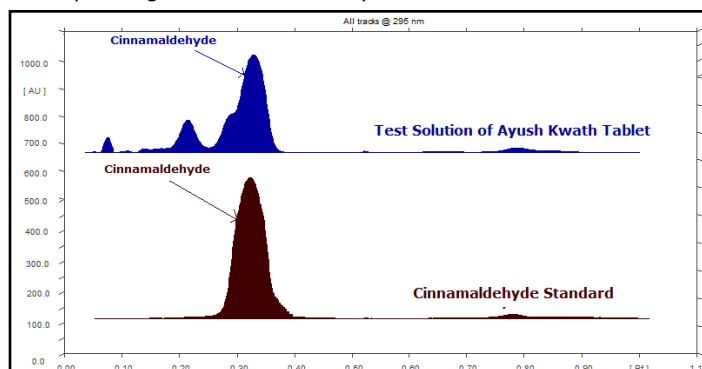
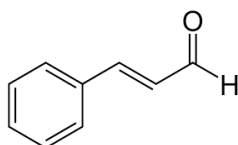
ii) Gingerol

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 568 nm corresponding with Gingerol standard.



iii) Cinnamaldehyde

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 295 nm corresponding with Cinnamaldehyde standard.

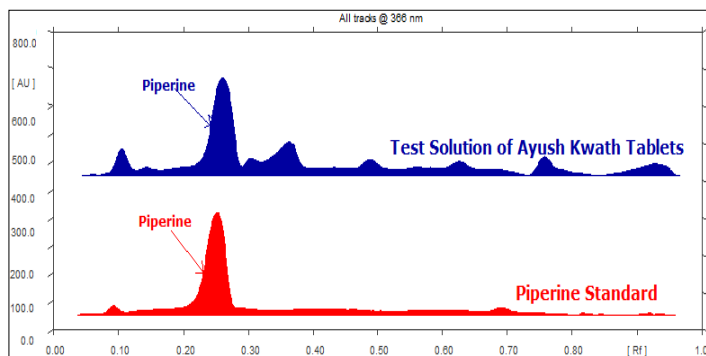
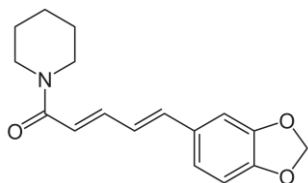


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iv) Piperine

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with Piperine standard.



Heavy metal

Lead (Pb)	NMT 10 ppm
Mercury (Hg)	NMT 1 ppm
Arsenic (As)	NMT 3 ppm
Cadmium (Cd)	NMT 0.3 ppm
<i>E. coli</i>	Absent/g
<i>P. aeruginosa</i>	Absent/g
<i>Salmonella sp.</i>	Absent/g
<i>Staphylococcus sp.</i>	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

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