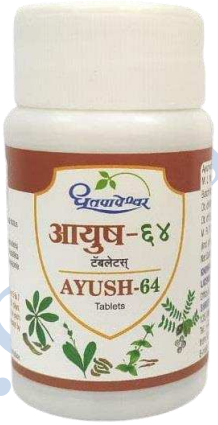
AYUSH-64 TABLETS

Monograph No. – 3100034 *ver 3.0*

Issue No: 03
Date of Issue: 19/06/2021
Text Reference : Know-How developed by CCRAS & Licensed by NRDC, New Delhi

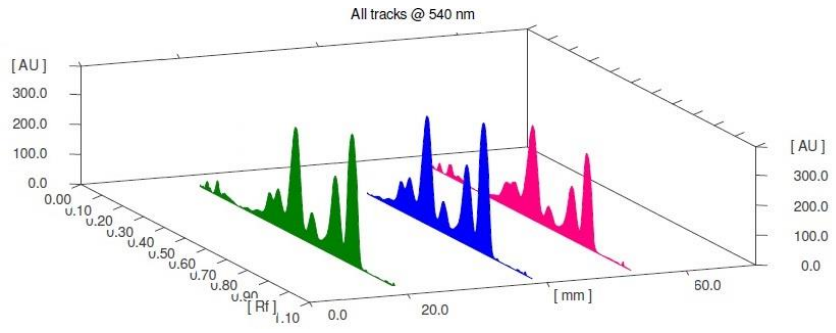
Amendment No : 00
Amendment Date : --
Shelf Life: 3 years



Description	Brown to Dark brown colour round biconvex tablets, having SDL mark on one side.
Loss on Drying at 105⁰	Not more than 6 % w/w
Hardness	Not less than 2 kg/cm^2
Thickness	5.5 ± 0.5 mm
Diameter	12.0 ± 0.5 mm
Friability	Not more than 1 % w/w
Disintegration Time	Not more than 30 min.
Average Weight	600 mg ± 5 %
Ash	Not more than 25 % w/w
Acid Insoluble Ash	Not more than 8 % w/w
Water Soluble Extractive	Not less than 30 % w/w
Alcohol Soluble Extractive	Not less than 5 % w/w
pH (1% Aq. Solution)	4 - 6.5
Uniformity of weight on 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 : Formic acid (5 : 4 : 1.6)
Details	Solvent of Extraction – Methanol Solvent front – 90 mm Total No. of Major spots – 6 Detection – Under UV at 366nm after spray with anisaldehyde sulfuric acid reagent

Major Spots	Colour	Approx. Rf.
1	Yellow	0.41
2	Light Yellow	0.46
3	Pink	0.53
4	Blue	0.61
5	Orange	0.71
6	Red	0.79

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

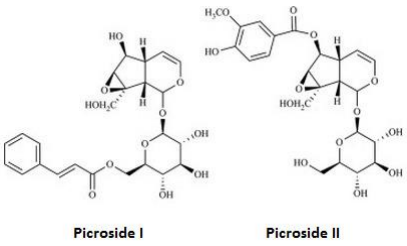


3D Peak Display of Ayush-64 Tablets at 540 nm

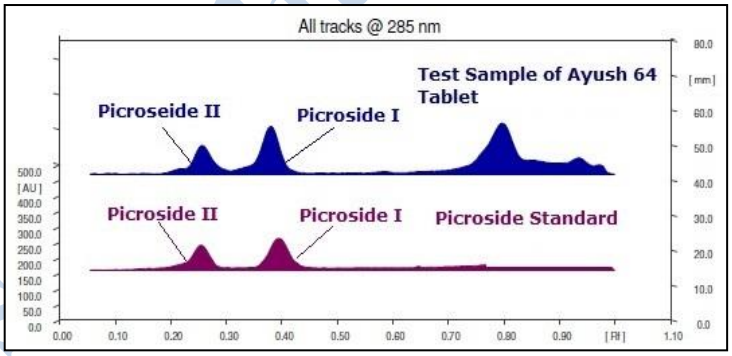
HPTLC Profile+

i) Picroside (I & II)

When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 285 nm for Picroside I & 285 nm for Picroside II corresponding with Picroside I & Picroside II standard.

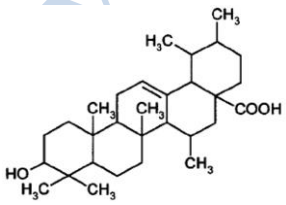


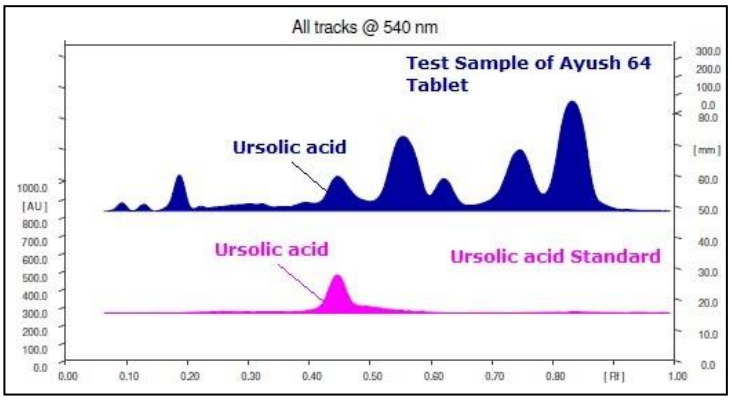
Picroside I Picroside II



ii) Ursolic acid

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 540 nm corresponding with Ursolic acid standard.





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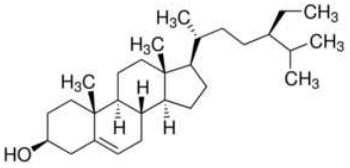
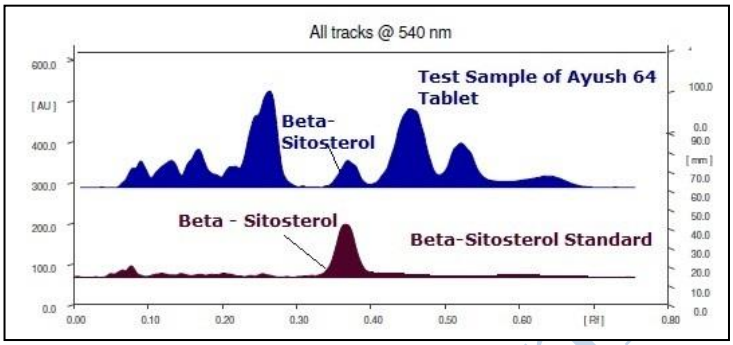
iii) Beta-Sitosterol

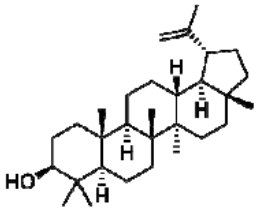
When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 540 nm corresponding with Beta-Sitosterol standard.

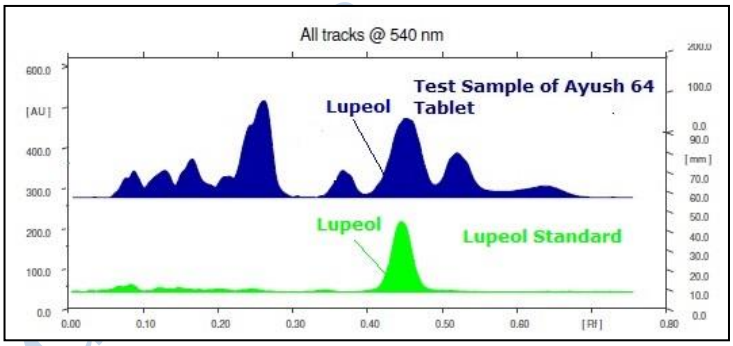




iv) Lupeol

When examined in the range of 400 nm to 700 nm, the test solution shows absorption maxima at about 540 nm corresponding with Lupeol 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†	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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