AMLA PLUS TABLETS

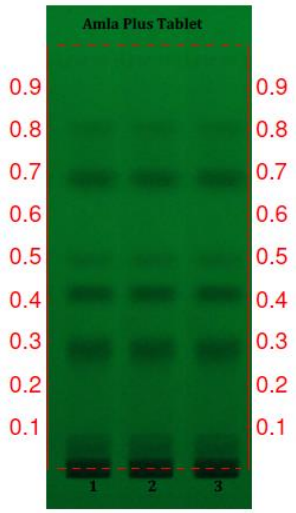
Monograph No. – 0703664 *ver 3.0*

Issue No: 03
Date of Issue: 03/10/2022
Text Reference : Ayurvedic Proprietary Medicine

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

Description	Light brown to brown coloured caplet shape coated tablets
Loss on Drying at 105⁰	Not more than 10 % w/w
Friability	Not more than 1 % w/w
Disintegration Time	Not more than 60 min.
Hardness	Not less than 2 kg/cm^2
Thickness	5.0 ± 0.5 mm
Length	17.5 ± 0.5 mm
Average Weight	705 mg ± 5 %
Uniformity of weight	Not more than 2 tablets deviate by more than 5 % of the average weight and none by more than 10 % of the average weight
Ash	Not more than 20 % w/w
Acid insoluble ash	Not more than 5 % w/w
Water soluble extractive	Not less than 25 % w/w
Alcohol soluble extractive	Not less than 10 % w/w
pH (1% aq. solution)	4.0 – 6.0
Thin Layer Chromatography Solvent system	Chloroform : Ethyl Acetate : Formic Acid (5 : 4 : 1.6)
Details	Solvent of Extraction – Methanol Distance traveled by solvent front – 90 mm Total No. of Major spots – 5 Visualization – Under UV at 254nm

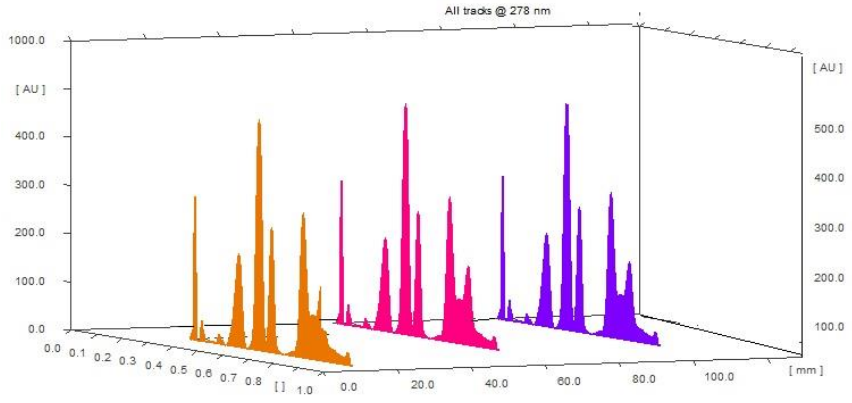




Major Spots	Color	Approx. Rf.
1	Black	0.29
2	Black	0.41
3	Light Gray	0.49
4	Gray	0.68
5	Light Gray	0.80

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

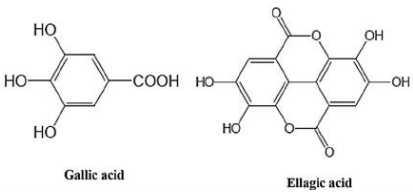


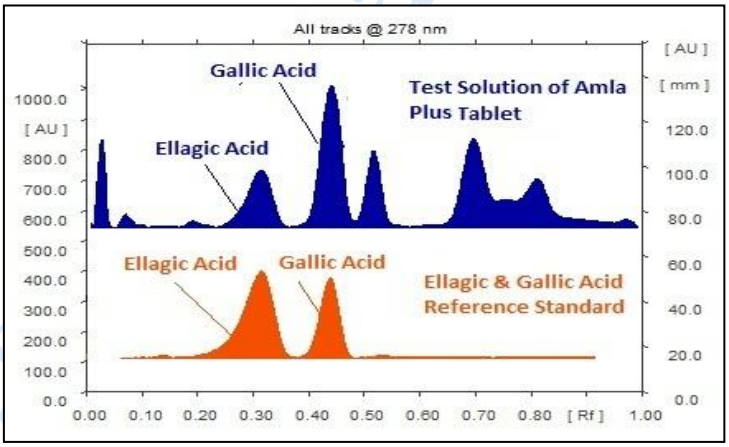
3D Peak Display of Amla Plus Tablets at 278 nm

HPTLC Profile †

i) Total Polyphenols (as Gallic acid & Ellagic acid)

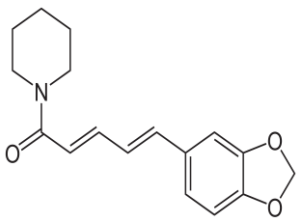
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid & 278 nm for Ellagic acid corresponding with Gallic acid & Ellagic acid standard.

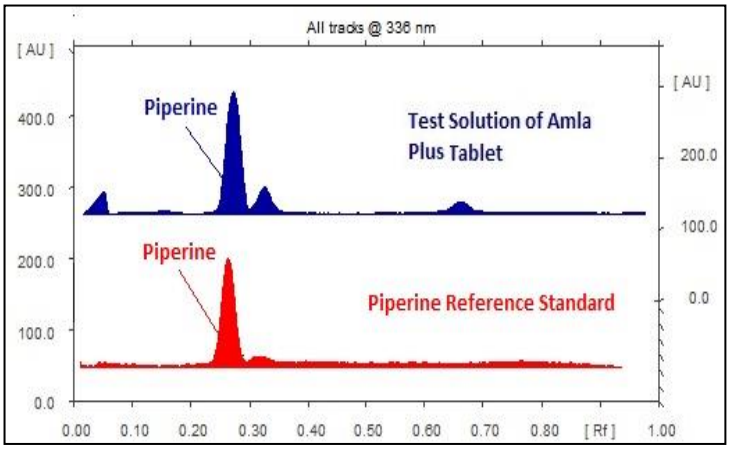




ii) Piperine

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.





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Heavy metal	
Lead (Pb)	Not more than 10 ppm
Mercury (Hg)	Not more than 1 ppm
Arsenic (As)	Not more than 3 ppm
Cadmium (Cd)	Not more than 0.3 ppm
E. coli	Absent/g
P. aeruginosa	Absent/g
Salmonella sp.	Absent/g
Staphylococcus sp.	Absent/g
Total Microbial plate count (TPC)	Not more than 10^5 c.f.u./g
Total Yeast & Mould count (TYMC)	Not more than 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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