

AMLA PLUS ZINC TABLET

Monograph No. – 0703674 ver 3.0

Issue No: 03

Date of Issue: 03/10/2022

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 01

Amendment Date : 28/03/2025

Shelf Life: 5 years

Description

Brown to dark brown coloured caplet shape coated tablets

Loss on Drying at 105°

Not more than 8 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 60 min.

Hardness

Not less than 2 kg/cm²

Thickness

5.0 ± 0.5 mm

Length

17.5 ± 0.5 mm

Average Weight

735 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 6 % w/w

Water soluble extractive

Not less than 25 % w/w

Alcohol soluble extractive

Not less than 5 % w/w

pH (1% aq. solution)

4.5 – 7.0

Elemental Assay

Zinc (Zn)

Not less than 15.0 mg/tablet

Thin Layer Chromatography Solvent system

Chloroform : Ethyl Acetate : Formic Acid
(5 : 4 : 1.6)

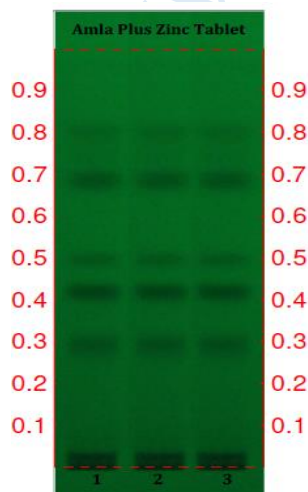
Details

Solvent of Extraction – Methanol

Distance traveled by solvent front – 90 mm

Total No. of Major spots – 5

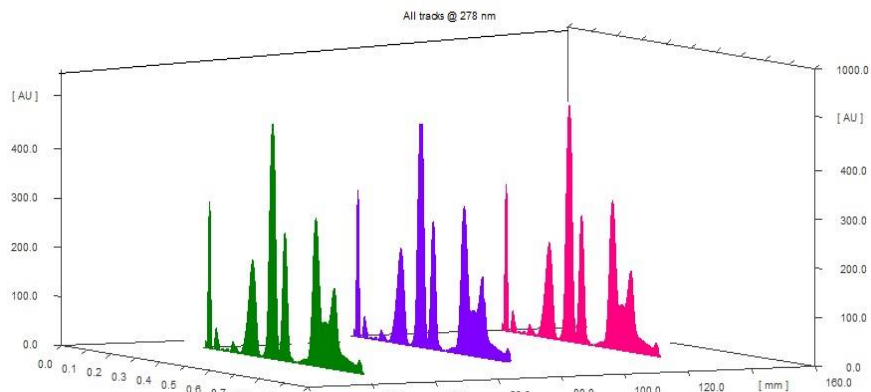
Visualization – Under UV at 254nm



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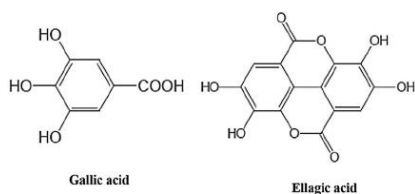
Note : [†] : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.



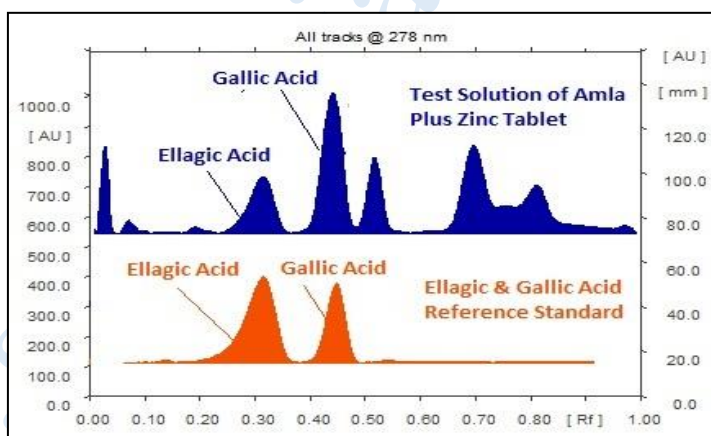
3D Peak Display of Amla Plus Zinc Tablets at 278 nm

HPTLC Profile [†]

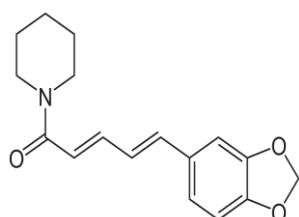
i) Total Polyphenols (as Gallic acid & Ellagic acid)



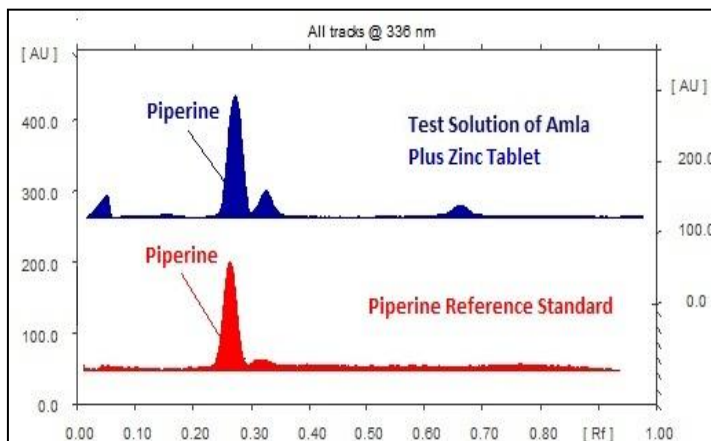
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid & 278 nm for Ellagic acid corresponding with Gallic acid & Ellagic acid standard.



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