

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 : 00

Amendment Date : --

Shelf Life: 3 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 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

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/tab

Thin Layer Chromatography Mobile Phase

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

Details

Solvent of Extraction – Methanol

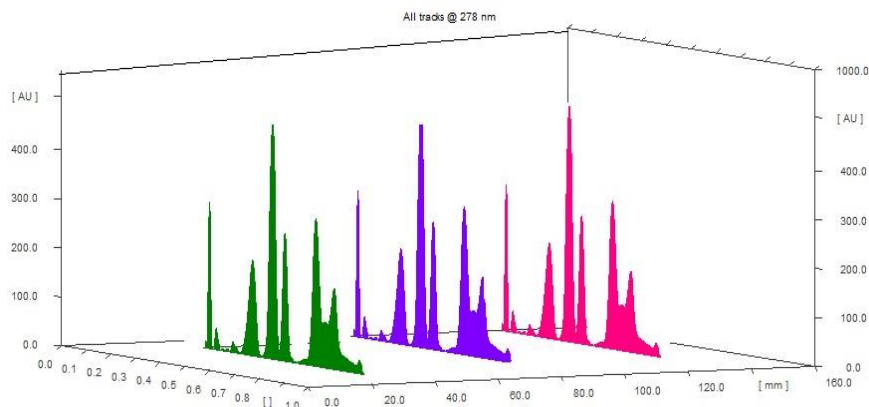
Distance traveled by solvent front – 90 mm

Total No. of Major spots – 5

Detection – 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



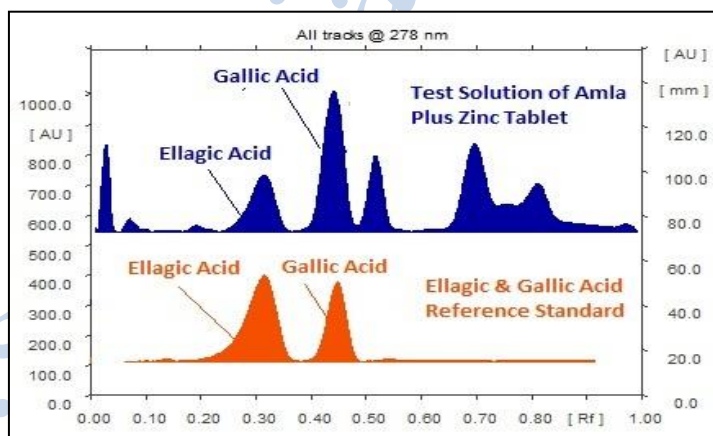
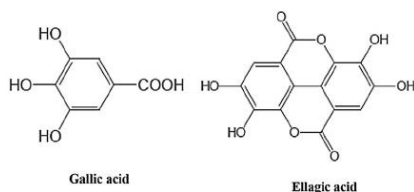


3D Peak Display of Amla Plus Zinc Tablets at 278 nm

HPTLC Profile [†]

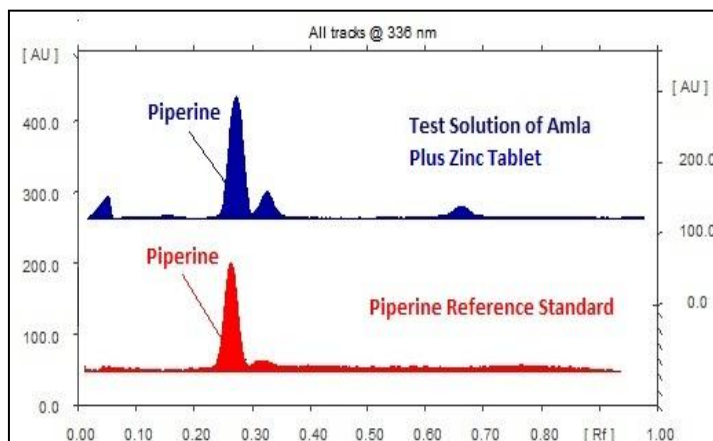
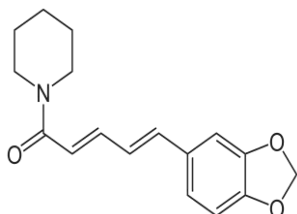
i) Total Polyphenols (as Gallic acid & Ellagic acid)

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.



<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

www.sdlindia.com