

ZPTER TABLET

Monograph No. – 070244 ver 3.0

Issue No: 03

Date of Issue: 28/10/2016

Text Reference : Ayurvedic Proprietary Medicine

Amendment No : 00

Amendment Date : --

Shelf Life: 5 years

Description

Faint olive green coloured round biconvex film coated tablets.

Loss on Drying at 105°

Not more than 6 % w/w

Hardness

Not less than 2.5 kg/cm²

Thickness

5.5 ± 0.5 mm

Diameter

12.0 – 12.5 mm

Disintegration Time

Not more than 60 mins.

Average Weight

686 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 25 % w/w

Acid insoluble ash

Not more than 6 % w/w

Water soluble extractive

Not less than 22 % w/w

Alcohol soluble extractive

Not less than 2.5 % w/w

Elemental Assay

Zinc (Zn)

7.0 – 12.0 mg/tab

Thin Layer Chromatography Mobile Phase

Chloroform : Ethanol : Glacial acetic acid
(9.4 : 0.5 : 0.1)

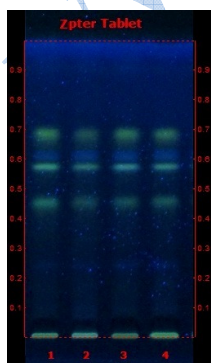
Details

Solvent of Extraction – Methanol

Solvent front – 90 mm

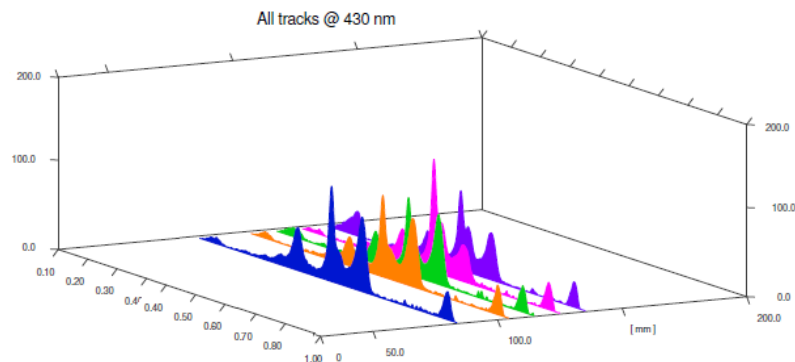
Total No. of Major spots – 5

Detection – Under UV at 366 nm



Major Spots	Colour	Approx. Rf.
1	Blue	0.23
2	Light Green	0.44
3	Yellow	0.58
4	Blue	0.61
5	Green	0.68

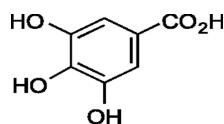




3D Peak Display of Zepter Tablet at 430 nm

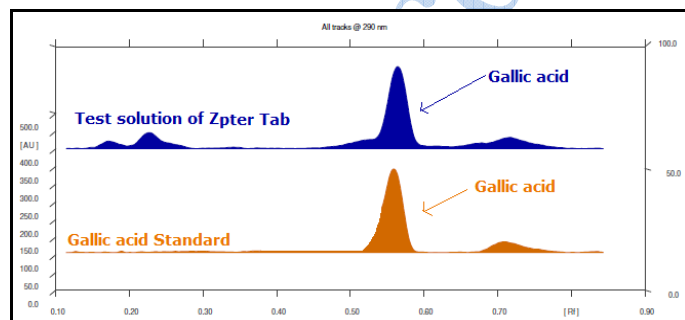
HPTLC Profile

i) Total Polyphenols (as Gallic acid)

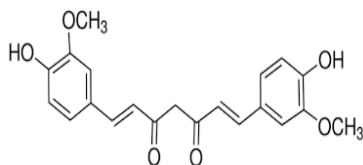


gallic acid (GA)

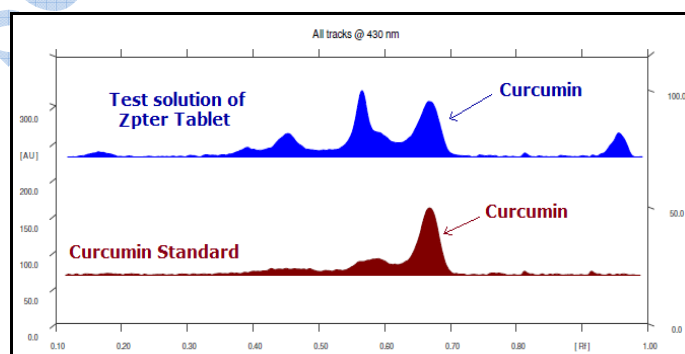
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 290 nm for Gallic acid corresponding with Gallic acid standard.



ii) Curcumin



When examined in the range of 200 nm to 700 nm, the test solution shows absorption maxima at about 430 nm corresponding with Curcumin standard.



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