


SHOOLAVAJRINI VATIKA

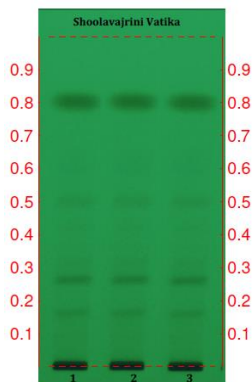
Monograph No. – 0802394 ver 3.0

Issue No: 03
Date of Issue: 16/11/2016
Text Reference : AFI Part 1-12/31

Amendment No : 02
Amendment Date : 14/07/2023
Shelf Life: 5 years

Description	Black colour, round convex coated tablet having SDL mark on one side.	
Loss on Drying at 105°	Not more than 6 % 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	5.5 ± 0.5 mm	
Diameter	8.0 ± 0.5 mm	
Average Weight	335 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 8 % w/w	
Water soluble extractive	Not less than 25 % w/w	
Alcohol soluble extractive	Not less than 15 % w/w	
pH (1 % Aq. Solution)	4.0 - 6.0	
Elemental Assay		
Iron (Fe)	Not less than 10 mg/tab	
Mercury (Hg)	15 - 24 mg/tab	
Copper (Cu)	4.8 - 7.2 mg/tab	
Sulphur (S)	18 - 27 mg/tab	
Thin Layer Chromatography		
Mobile Phase	Toluene : Ethyl acetate (7 : 3)	

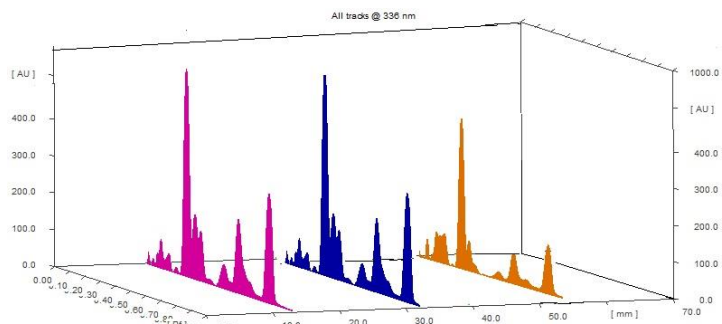
Details



Solvent of Extraction – Methanol
Solvent front – 90 mm
Total No. of Major spots – 4
Detection – Under UV at 254 nm

Major Spots	Colour	Approx. Rf.
1	Light Gray	0.16
2	Gray	0.27
3	Light Gray	0.50
4	Gray	0.80

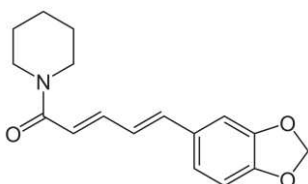
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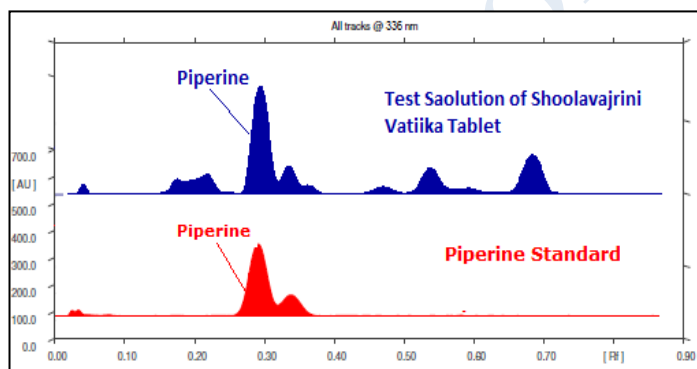
3D Peak Display of Shoolavajrini Vatika at 336 nm

HPTLC Profile[†]

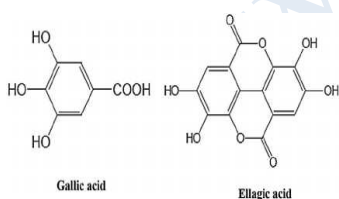
i) Piperine



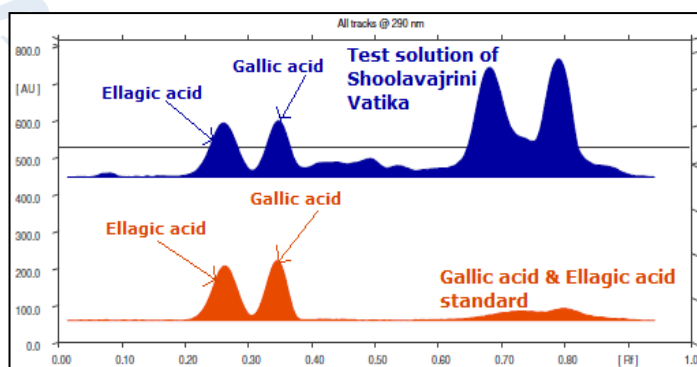
When examined in the range of 200 nm to 400 nm, the test solution shows absorption maxima at about 336 nm corresponding with Piperine standard.



ii) 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.



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 (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

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