

SOOTIKABHARAN RASA (TABLET) (PREMIUM)

Monograph No. – 0900134 ver 3.0

Issue No: 03

Date of Issue: 09/09/2017

Text Reference : Bharat Bhaishajya Ratnakar 5/8267

Amendment No : 02

Amendment Date : 25/11/2021

Shelf Life: 5 years

Description

Gray to dark gray colour, round convex coated tablet having SDL mark on one side.

Loss on Drying at 105°

Not more than 5 % w/w

Friability

Not more than 1 % w/w

Disintegration Time

Not more than 60 min.

Hardness

Not less than 1.5 kg/cm²

Thickness

3.0 ± 0.5 mm

Diameter

6.5 ± 0.5 mm

Average Weight

162 mg ± 7.5 %

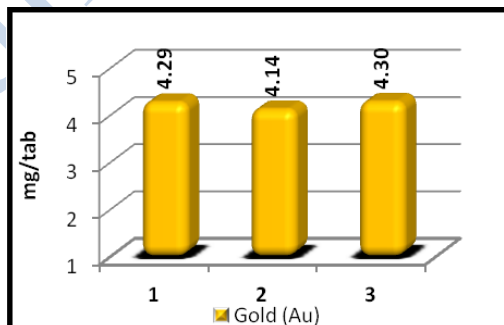
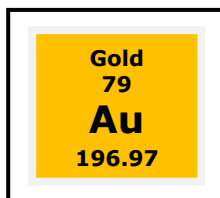
Uniformity of weight of 20 tablets

Not more than two of the individual weights deviate from the average weight by more than 7.5 %.

Elemental assay

Gold (Au)

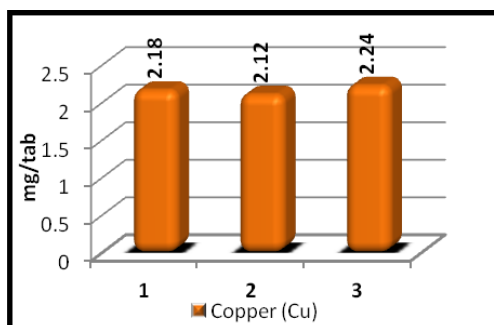
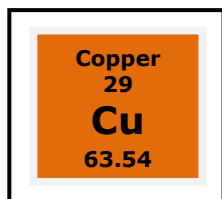
3.0 – 5.5 mg/tab



Graphical Representation of Gold Content in Sootikabharan Rasa (Batch to Batch Consistency) by ICP-OES

Copper (Cu)

1.5 – 3.5 mg/tab



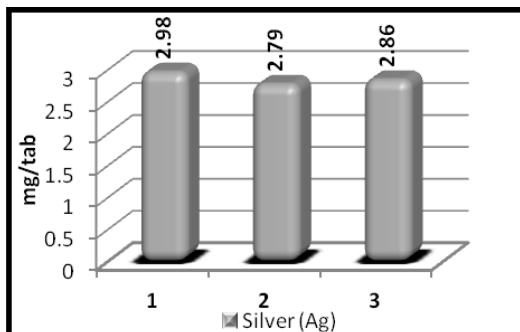
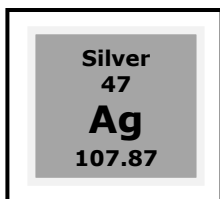
Graphical Representation of Copper Content in Sootikabharan Rasa (Batch to Batch Consistency) by ICP-OES

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

Silver (Ag)

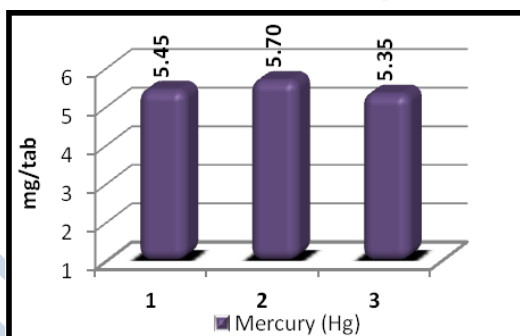
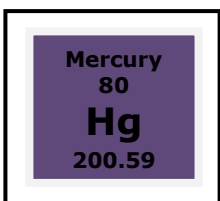
2.0 – 4.5 mg/tab



Graphical Representation of Silver Content in Sootikabharan Rasa (Batch to Batch Consistency) by ICP-OES

Mercury (Hg)

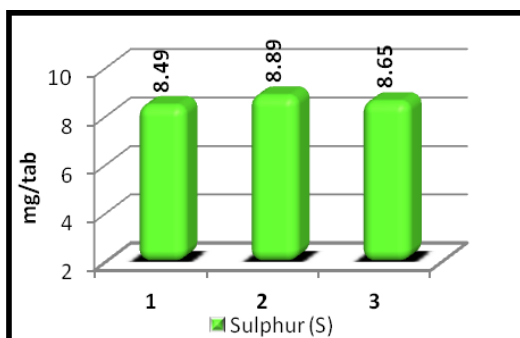
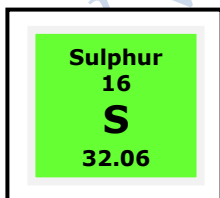
3.5 – 6.0 mg/tab



Graphical Representation of Mercury Content in Sootikabharan Rasa (Batch to Batch Consistency) by ICP-OES

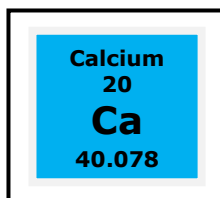
Sulphur (S)

7.0 – 11.0 mg/tab

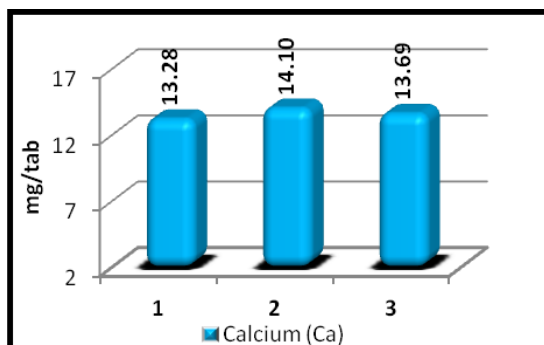


Graphical Representation of Sulphur Content in Sootikabharan Rasa (Batch to Batch Consistency)

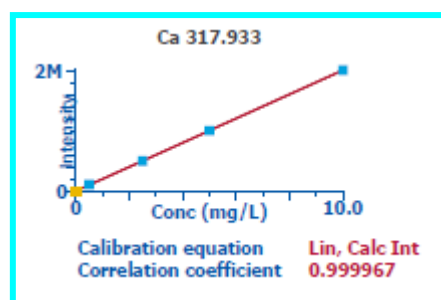
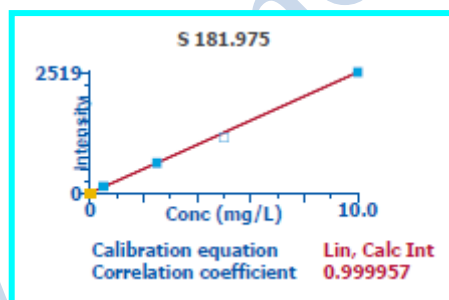
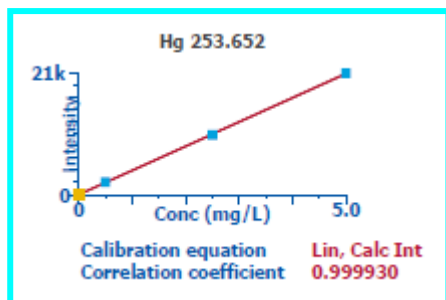
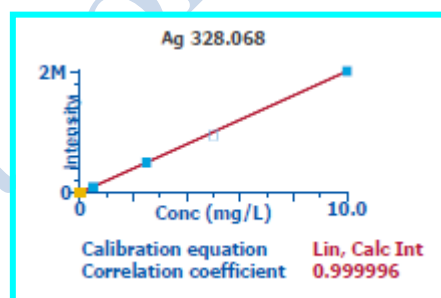
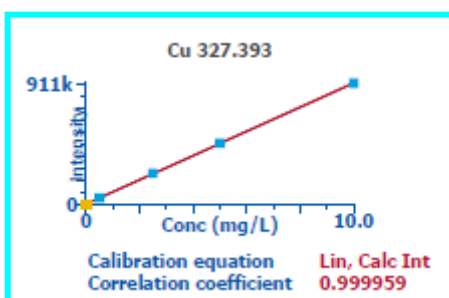
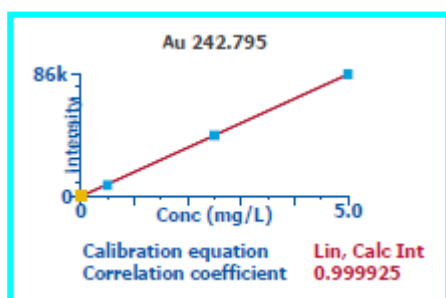
Calcium (Ca)



Not less than 1.5 mg/tab



Graphical Representation of Calcium Content in Sootikabharan Rasa (Batch to Batch Consistency) by ICP-OES



Standard Linear Graph of Au, Cu, Ag, Hg, S & Ca prepared in correlation with NIST Traceable Reference Standard

Acute Toxicity	Nontoxic when single dose (10 x therapeutic dose) administered orally
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