

KUMARKALYAN RASA (TABLET) (PREMIUM)

Monograph No. – 0900084 ver 3.0

Issue No: 03

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Text Reference : Bhaishajya Ratnavali (Balaroga) 71/119-122

Amendment No : 02

Amendment Date : 25/11/2021

Shelf Life: 5 years

Description

Brown to dark brown 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.

Thickness

3.0 ± 0.5 mm

Diameter

6.5 ± 0.5 mm

Hardness

Not less than 1.5 kg/cm²

Average Weight

156 mg ± 7.5 %

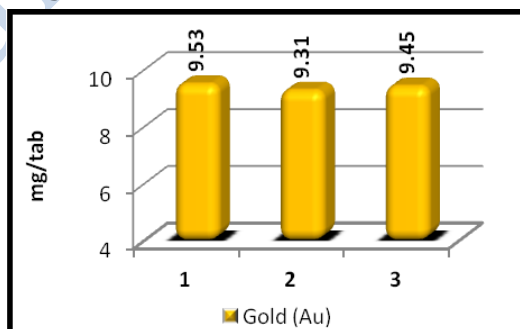
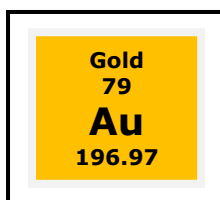
Uniformity of weight of 20 tablets

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

Elemental assay

Gold (Au)

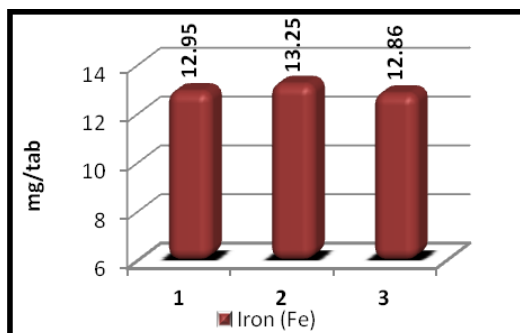
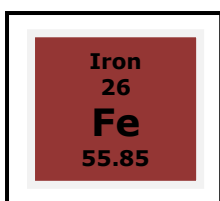
8.5 – 10.5 mg/tab



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

Iron (Fe)

10.5 – 15.5 mg/tab



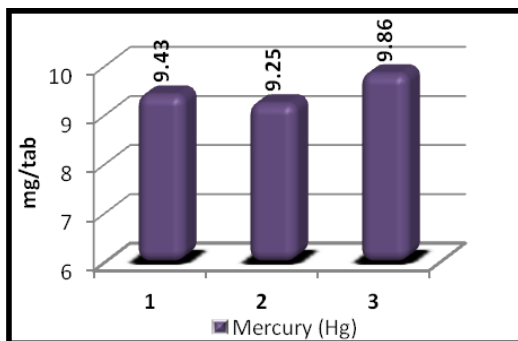
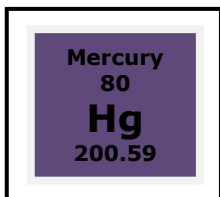
Graphical Representation of Iron Content in Kumarkalyan Rasa (Batch to Batch Consistency) by ICP-OES

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

Mercury (Hg)

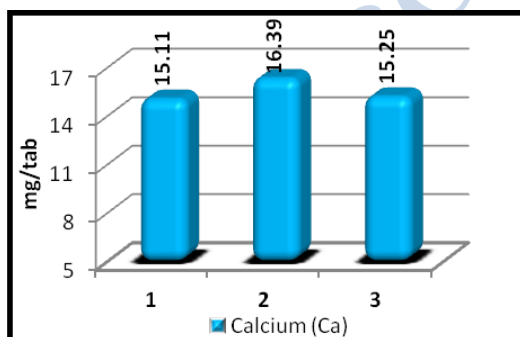
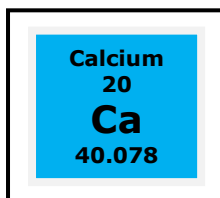
6.0 – 10.0 mg/tab



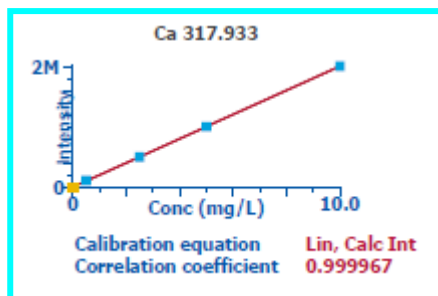
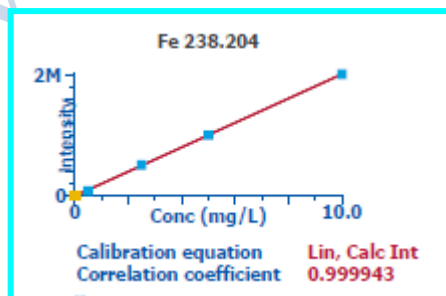
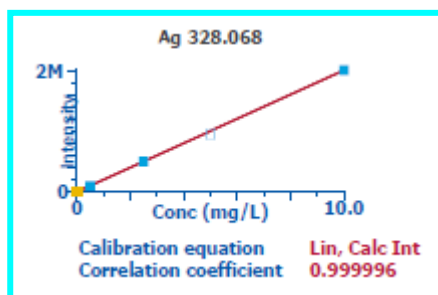
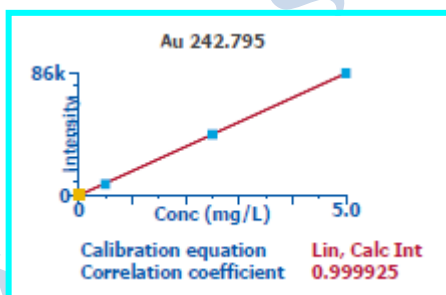
Graphical Representation of Mercury Content in Kumarkalyan Rasa (Batch to Batch Consistency) by ICP-OES

Calcium (Ca)

Not less than 5 mg/tab



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



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

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

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

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