

## BRUHAT KASTOORI BHAIRAV (TABLET) (PREMIUM)

Monograph No. – 0900044 ver 3.0

Issue No: 03

Amendment No : 02

Date of Issue: 09/09/2017

Amendment Date : 25/11/2021

Text Reference : Bharat Bhaishajya Ratnakar 4/7108

Shelf Life: 5 years

### Description

Gray to dark gray colour, round convex coated tablets 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/cm<sup>2</sup>

### Thickness

3.0 ± 0.5 mm

### Diameter

6.5 ± 0.5 mm

### Average weight

156 mg ± 7.5 %

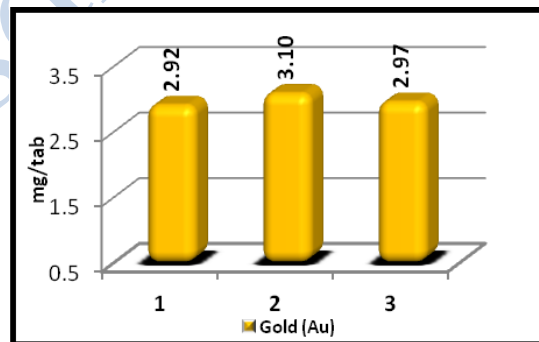
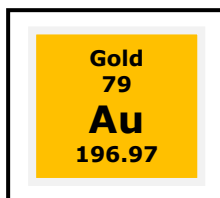
### Uniformity of weight of 20 tablets

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

### Elemental assay

#### Gold (Au)

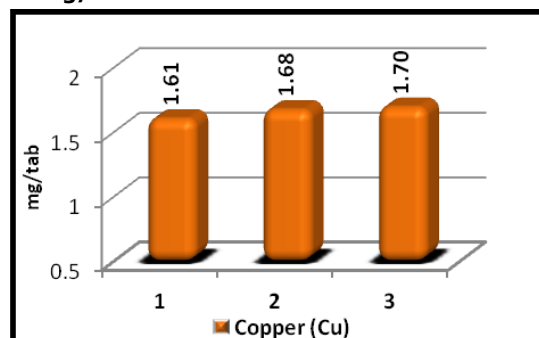
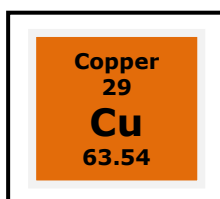
2.0 – 4.0 mg/tab



Graphical Representation of Gold Content in Bruhat Kastoori Bhairav (Batch to Batch Consistency) by ICP-OES

#### Copper (Cu)

1.0 – 2.5 mg/tab



Graphical Representation of Copper Content in Bruhat Kastoori Bhairav (Batch to Batch Consistency) by ICP-OES

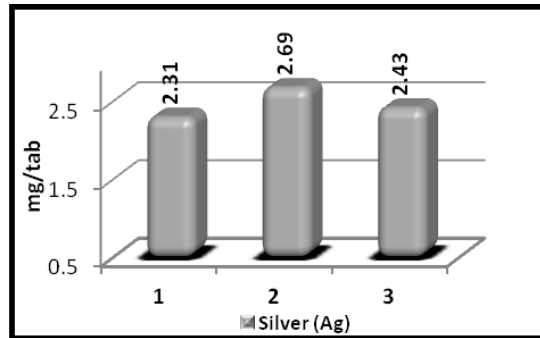
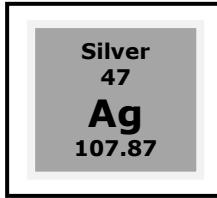
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Note : † : These extra tests can be performed on every batch at extra cost. Tests can be ascertained on request.

## Silver (Ag)

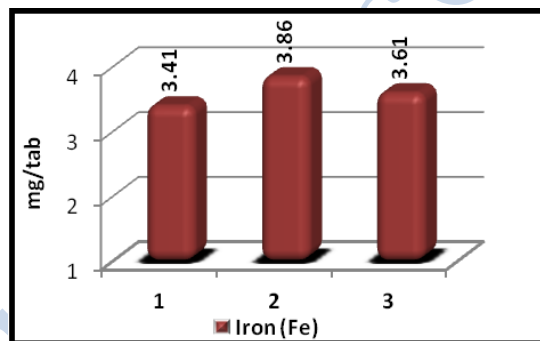
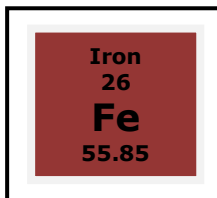
1.0 – 3.0 mg/tab



Graphical Representation of Silver Content in Bruhat Kastoori Bhairav (Batch to Batch Consistency) by ICP-OES

## Iron (Fe)

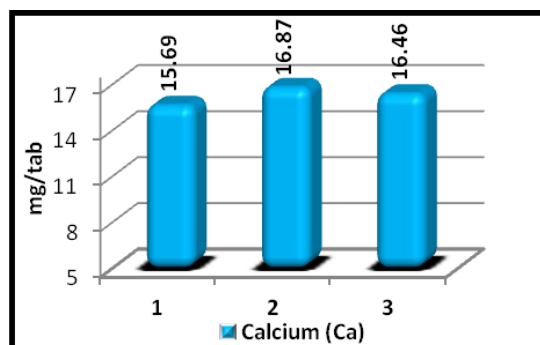
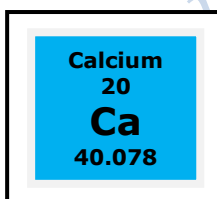
2.0 – 4.0 mg/tab



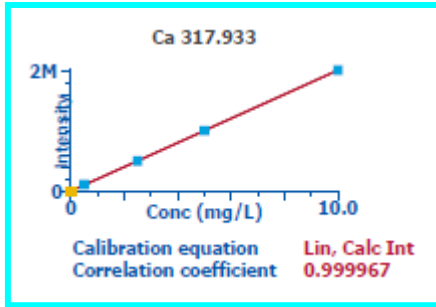
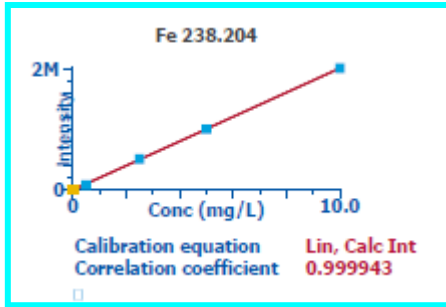
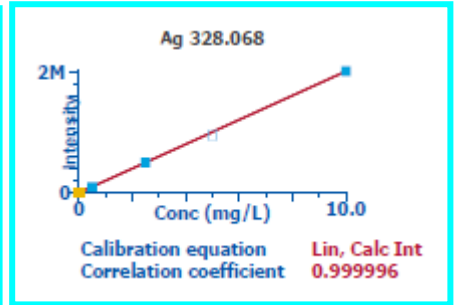
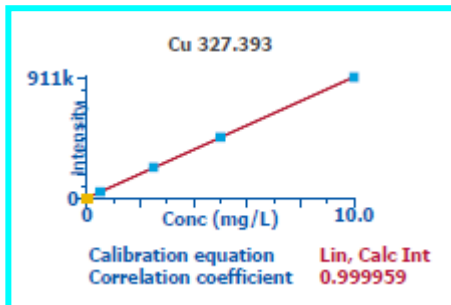
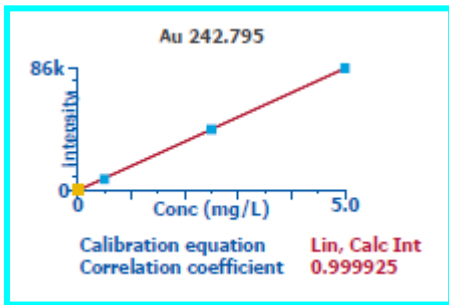
Graphical Representation of Iron Content in Bruhat Kastoori Bhairav (Batch to Batch Consistency) by ICP-OES

## Calcium (Ca)

Not less than 3 mg/tab



Graphical Representation of Calcium Content in Bruhat Kastoori Bhairav (Batch to Batch Consistency) by ICP-OES



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

|  |   |
|--|---|
| <b>Acute Toxicity</b>                        | Nontoxic when single dose (10 x therapeutic dose) administered orally |
| <b>E. coli</b>                               | Absent/g  |
| <b>P. aeruginosa</b>                         | Absent/g  |
| <b>Salmonella sp.</b>                        | Absent/g  |
| <b>Staphylococcus sp.</b>                    | Absent/g  |
| <b>Total Microbial plate count (TPC)</b>     | NMT 10 <sup>5</sup> c.f.u./g  |
| <b>Total Yeast &amp; Mould Count (TYMC)</b>  | NMT 10 <sup>3</sup> c.f.u./g  |
| <b>Pesticide Residue<sup>†</sup> (OC+OP)</b> | Complies as per API   |
| <b>Aflatoxins B1,B2,G1,G2<sup>†</sup></b>    | Complies as per API   |