

Shree Dhootapapeshwar Standards

DUGDHA VATI

Monograph No. - 0802514 ver 3.0

Issue No: 03 Date of Issue: 17/11/2023 Text Reference : Bharat Bhaishajya Ratnakar 3/3212 Amendment No : 01 Amendment Date : 24/05/2024 Shelf Life: 5 years

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Description	Peach pink to brick red colour, round biconvex coated tablets having SDL mark on one side.
Loss on Drying at 105 ⁰	Not more than 7 % 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	4.8 <u>+</u> 0.5 mm
Diameter	8.0 <u>+</u> 0.5 mm
Average Weight	302.5 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 33 % w/w
Acid insoluble ash	Not more than 5 % w/w
Water soluble extractive	Not less than 18 % w/w
Alcohol soluble extractive	Not less than 2.5 % w/w
pH (1 % Aq. Solution)	6.5 - 8.5
Elemental Assay	
Mercury (Hg)	Not less than 11.0 mg/tablet
Sulphur (S)	Not less than 2.0 mg/tablet
E. coli	Absent/g
P. aeruginosa	Absent/g
Salmonella sp.	Absent/g
Staphylococcus sp.	Absent/g
Total Microbial plate count (TPC)	Not more than 10 ⁵ c.f.u./g
Total Yeast & Mould count (TYMC)	Not more than 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.