



KERALA STATE DRUGS AND PHARMACEUTICALS LTD.

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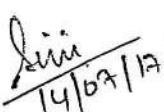

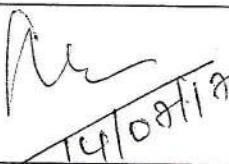

RAW MATERIAL SPECIFICATION

NAME OF THE MATERIAL: EMPTY HARD GELATIN CAPSULE SHELL IP SIZE "0" Green/Green

SOP NO: KSDP/SOP/SPEC01

RECORD NO: KSDP/R/SPEC01/56

S.NO	TESTS	SPECIFICATION
1	Description	Empty hard gelatin capsule shell consists of two cylindrical, telescoping pieces (cap and body), one end of which is rounded and closed and the other, open. The cap overlaps the body and maintains a tight friction closure. The shells are smooth and uniform in size, shape and colour. The pieces are of green and green coloured with size "0" unprinted on it.
2	Identification	Boil one capsule shell with 20ml of water, allow to cool and centrifuge. To 5ml of the supernatant liquid add 1ml of picric acid solution and to another 5ml add 1ml of tannic acid solution; a precipitate is produced in each case.
3	Odour	The shell do not develop any foreign odour
4	Average weight	Within $\pm 10\%$
5	Disintegration	15 minutes
6	Microbial contamination	Total microbial count, not more than 1000per g; 1g is free from Escherichia coli; 10 g is free from Salmonellae and Shigella
7	Loss on drying	12.5 to 16 %, determined on 1.0g by drying in an oven at 105° for 4 hours or to constant weight.

Prepared by	Checked by	Reviewed By	Approved By
Junior Manager QA	Production Head	QC Head	QA Head
 14/07/17		 14/07/17	 14/07/17

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