



## CERTIFICATE OF ANALYSIS

References if any:

|                         |   |                          |  |                          |             |
|-------------------------|---|--------------------------|--|--------------------------|-------------|
| <b>Customer Name:</b>   |   | <b>C.O. A. No:</b>       |  |                          |             |
|                         |   | <b>Date:</b>             |  |                          |             |
|                         |   | <b>Page No. 01 of 02</b> |  |                          |             |
| <b>Name of Product:</b> | <b>Empty Hard Gelatin Capsules Shell (I.P.)</b> | <b>Mfg. Date:</b>        |  | <b>Qty.</b>              |             |
| <b>Batch No.</b>        |   | <b>Expiry Date:</b>      |  | <b>Order No.</b>         |             |
| <b>Colour Code</b>      | <b>Cap:</b>                                     | <b>Printing</b>          |  | <b>Size of Capsules:</b> | <b>ZERO</b> |
|                         | <b>Body:</b>                                    |                          |  |                          |             |

|                                |  |
|--------------------------------|--|
| <b>Empty Capsules Contents</b> | Gelatin  |
|                                | Water  |
|                                | Sodium Lauryl Sulphate                         |
|                                | Preservatives (Methyl paraben, Propyl paraben) |

| <b>Colours Used</b> |                 |             |                 |
|---------------------|-----------------|-------------|-----------------|
| <b>Cap</b>          | <b>C.I. No.</b> | <b>Body</b> | <b>C.I. No.</b> |
|                     |                 |             |                 |
|                     |                 |             |                 |
|                     |                 |             |                 |
|                     |                 |             |                 |
|                     |                 |             |                 |
|                     |                 |             |                 |

|                       |  |
|-----------------------|--|
| <b>Gelatin Used :</b> |  |
|-----------------------|--|

**NOTE : Gelatin used is free of B.S.E. & T.S.E**

|                            |               |                         |               |
|----------------------------|---------------|-------------------------|---------------|
| <b>Printing Ink Colour</b> | <b>Cap :</b>  | <b>Printing Message</b> | <b>Cap :</b>  |
|                            | <b>Body :</b> |                         | <b>Body :</b> |

## << ANALYSIS >>

COA no:

page - 2

| TEST | SPECIFICATION | METHOD | RESULT |
|------|---------------|--------|--------|
|------|---------------|--------|--------|

### PHYSICAL TESTS

|                      |   |            |             |
|----------------------|---|------------|-------------|
| Description          | Cylindrical, Opaque, Telescopic Capsules, Transparent       | I.P.       | Complies    |
| Identification       | Passes as per (I.P.)  | I.P.       | Complies    |
| Av. Wt. Of Capsules  | 96 Mg $\pm$ 07%   | I.P.       | 96.7 Mgs    |
| Disintegration Time  | Less Than 15 Minutes  | I.P.       | 9:50 Minute |
| Loss on Drying       | 12.5 % - 16.0 %   | I.P. / USP | 14.0-15.0 % |
| Self Locking Feature | Shell and body lock together and are not readily separated. | EPL        | Complies    |
| Brittleness          | Shell deforms under pressure but dies not crack             | EPL        | Complies    |

### MICROBIOLOGICAL TESTS

|                       |                         |            |           |
|-----------------------|-------------------------|------------|-----------|
| Total Bacterial Count | Less Than 1000 cfu / gm | I.P. / USP | 54 Cfu/gm |
| Escherichia Coli      | Absent                  | I.P. / USP | Absent    |
| Salmonella            | Absent                  | I.P. / USP | Absent    |
| Staphylococcus Aureus | Absent                  | I.P. / USP | Absent    |
| Pseudomonas           | Absent                  | I.P. / USP | Absent    |
| Yeast and Moulds      | Absent                  | I.P. / USP | Absent    |

### DIMENSIONS

|                            | Cap                 | Body                | Method | Result   |
|----------------------------|---------------------|---------------------|--------|----------|
| Length                     | 11.18 $\pm$ 0.5 mm  | 18.72 $\pm$ 0.5mm   | I.P.   | Complies |
| Double Wall Thickness      | 0.205 $\pm$ 0.018mm | 0.195 $\pm$ 0.018mm | I.P.   | Complies |
| Outside Diameter           | 7.63 $\pm$ 0.06mm   | 7.32 $\pm$ 0.06mm   | I.P.   | Complies |
| Prelock Length of Capsules | 23.6 $\pm$ 0.4mm    |                     | EPL    | Complies |
| Closed Joined Length       | 21.8 $\pm$ 0.4mm    |                     | EPL    | Complies |

**Remark :** Above sample complies to the test and specification mentioned.

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(Q.C. LAB)

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(F.Q.C. INCHARGE)

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(Q.C. DEPARTMENT)