



# ZEE LABORATORIES LTD

Behind 47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT) (The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. :

Document No. : 252652012

|              |                            |                  |            |
|--------------|----------------------------|------------------|------------|
| Ref. STS No. | 514                        | Product Code     | FG03215    |
| Product Name | TAB. BETASONE              |                  |            |
| Generic Name | BETAMETHASONE TABLETS I.P. |                  |            |
| Batch No.    | 426-188                    | Date Of Sampling | 13/02/2026 |
| Batch Size   | 200000.000 Tab             | Sample Quantity  | 60.000 Tab |
| Mfg. Date    | 01/2026                    | Exp. Date        | 12/2028    |
| A. R. No.    | ZL26FG01244                | Date Of Release  | 27/02/2026 |

| S NO. | Tests                                                        | Specification                                                                                                                                                        | Results      |
|-------|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 1     | Description                                                  | White colour, rounded biconvex uncoated tablet. one side smooth and other side scored.                                                                               | Complies     |
| 2     | Identification                                               | The principal spot in the chromatogram obtained with reference solution (b) appears as a single, compact spot and the chromatogram obtained with reference solution. | Complies     |
| 3     | Average weight of Tablet                                     | 80.0 mg $\pm$ 7.5 %                                                                                                                                                  | 80.7 mg      |
| 4     | Uniformity of Weight                                         | $\pm$ 7.5 % of the average weight                                                                                                                                    | Complies     |
| 5     | Disintegration Test                                          | Not more than 15 minutes                                                                                                                                             | 00:40 Min    |
| 6     | Friability test                                              | NMT 1.0%w/w                                                                                                                                                          | 0.36 %       |
| 7     | Uniformity of content                                        | Not less than 75% and not more than 125% of the labeled amount of Betamethasone.                                                                                     | 89% to 97 %  |
| 8     | Dissolution (%)                                              | NLT 75 (Q) of the labeled amount of betamethasone dissolved on 45 minutes at 50 rpm.                                                                                 | 81% to 104 % |
| 9     | Assay Each uncoated tablet contains Betamethasone I.P. 0.5mg | NLT 90.0 % and NMT 110.0 % of the labeled amount                                                                                                                     | 97.9 %       |

**Remarks** The above sample complies/does not comply with prescribed standards of Quality with respect to above tests as per IP/BP/USP/In house specification.

| Particulars  | Analysis By                                                                                  | Prepared By                                                                                    | Checked By                                                                                     | Approved By                                                                                    |
|--------------|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Sign & Date  |  27/02/26 |  27/02/2026 |  27/02/26 |  27/02/26 |
| Name:        | Nitin                                                                                        | Raghuveer                                                                                      | qcm                                                                                            | Dheeraj                                                                                        |
| Designation: | Officer QC                                                                                   | Officer QC                                                                                     | Staff                                                                                          | Arti Manager                                                                                   |