




CERTIFICATE OF ANALYSIS

| | | | |
|-------------------------|----------------|-------------------------|---------------------|
| Batch No. | : TC3081A | Product Name | : IRBESARTAN -300MG |
| Batch size | : 30000Tablets | Reference | : USP |
| Mfg. date | : 03-2023 | Sampled Quantity | : 60 TAB |
| Exp. Date | : 02-2026 | AR. No. | : NFP/2202356 |
| Date of Analysis | : 28-03-2023 | Date of Release | : 05-04-2023 |

| S. No. | Tests | Specifications | Results |
|--------|---|--|--|
| 1. | Description | White or off white colour round shaped biconvex scored on one side and plain on another & film coated tablets. | A White colour round shaped biconvex break line on one side film coated tablets. |
| 2. | Identification | | |
| | By(IR) | The IR absorption spectrum of the test preparation should exhibits maxima at the same wavelength as that of a similar preparation of Irbesartan working standard. | The IR absorption spectrum of the test preparation should exhibits maxima at the same wavelength as that of a similar preparation of Irbesartan working standard |
| | By (HPLC) | The relative retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay. | The relative retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay. |
| 3. | Average weight | 420.0 mg±5.0% | 438.64mg |
| 4. | Uniformity of Weight | ±5.0% of average weight | -1.52% to + 2.56% |
| 5. | Dissolution | NLT 80%(Q)dissolved in 20 minutes | 86.23% to 87.90 % |
| 6. | Related compounds | | |
| | Irbesartan related compound A | NMT 0.2% | Complies |
| | Individual impurity | NMT 0.2% | Complies |
| | Total impurity | NMT 0.5% | Complies |
| 7. | NDMA,NDEA y NMBA | | |
| | NDEA-N- Nitrosodiethylamine | NMT 0.088 ppm | Complies |
| | NDMA-N- Nitrosodiethylamine | NMT 0.32ppm | Complies |
| | NMBA-Acid-N-Nitroso-N-Methylamino Butyric | NMT 0.32ppm | Complies |
| 8. | Assay Irbesartan USP.. -300mg | 90.0% to 110% of label claim. | 98.54% |

| Particulars | Prepared By | Checked By | Approved By |
|-------------|---|--|---|
| Name | Hasib Ansari | Kamaljeet | Bhaskar Shinagare |
| Designation | Officer QC | Executive QC | Manager QC |
| Sign & Date |  |  |  |










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| 9. | Microbiological count | Aerobic bacterial count:NMT 10 ³ /1g yeast& fungal count:NMT 10 ² /1g pathogen E.coli,Salmonella etc: Absent | 30CFU/g Less than 10CFU/g Absent |
| 10. | Packing | 10 Tablets in a aluminium blister.3 blister are packed in a carton unit with the instruction for medical use. | Complies |
| 11. | Storage | Protect from light and moisture.Store at the temperature below 30°C. | |
| 12. | Shelf Life | 3 years from the date of manufacturing. | |

Remark Complies as per the specification.

| Particulars | Prepared By | Checked By | Approved By |
|-------------|---|--|---|
| Name | Hasib Ansari | Kamaljeet | Bhaskar Shinagare |
| Designation | Officer QC | Executive QC | Manager QC |
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