






NAV KAR LIFESCIENCES
Plot no.: 76, Industrial Area, Lodhimajra, Baddi, Distt.: Solan (H.P.)

CERTIFICATE OF ANALYSIS

Batch No.	: TG3001A	Product Name	: IRBESARTAN -150MG
Batch size	: 1.555 Lac Tablets	Reference	: USP
Mfg. date	: 07-2023	Sampled Quantity	: 60 TAB
Exp. Date	: 06-2026	AR. No.	: NFP/2301440
Date of Analysis	: 27-07-2023	Date of Release	: 04-08-2023

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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		
3.	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
4.	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.
5.	Average weight	300.0 mg \pm 5.0%	302.58mg
6.	Uniformity of Weight	\pm 5.0% of average weight	-1.45% to +1.49%
7.	Dissolution	NLT 80%(Q)dissolved in 20 minutes	92.62% to 95.04%
8.	Related compounds		
9.	Irbesartan related compound A	NMT 0.2%	Complies
10.	Individual impurity	NMT 0.2%	Complies
11.	Total impurity	NMT 0.5%	Complies
12.	NDMA,NDEA y NMBA		
13.	NDEA-N- Nitrosodiethylamine	NMT 0.088 ppm	Complies
14.	NDMA-N- Nitrosodiethylamine	NMT 0.32ppm	Complies
15.	NMBA-Acid-N-Nitroso-N-Methylamino Butyric	NMT 0.32ppm	Complies
16.	Assay	90.0% to 110% of label claim.	99.41%

Particulars	Prepared By	Checked By	Approved By
Name	Hasib Ansari	Sushil Tiwari	Bhaskar Shinagare
Designation	Officer QC	Asst. Manager QC	Manager QC
Sign & Date			



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17.	Microbiological count	Aerobic bacterial count: NMT 10^3 /g yeast & fungal count: NMT 10^2 /g pathogen E.coli, Salmonella etc: Absent	32CFU/g Less than 10CFU/g Absent
18.	Packing	10 Tablets in a aluminium blister. 3 blister are packed in a carton unit with the instruction for medical use.	Complies
19.	Storage	Protect from light and moisture. Store at the temperature below 30°C.	
20.	Shelf Life	3 years from the date of manufacturing.	

Remarks: Conforms to the Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Hasib Ansari	Sushil Tiwari	Bhaskar Shinagare
Designation	Officer QC	Asst. Manager QC	Manager QC
Sign & Date	 5/8/23	 5-8-23	 5-8-2023