



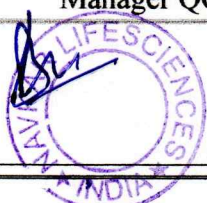
NAV KAR LIFESCIENCES
Plot no.: 76, Industrial Area, Lodhimajra, Baddi, Distt.: Solan (H.P.)

CERTIFICATE OF ANALYSIS

Batch No.	: TK5002A	Product Name	: IRBESARTAN -300MG
Batch size	: 0.92 Lac Tablets	Reference	: USP
Mfg. date	: 11-2025	Sampled Quantity	: 60 TAB
Exp. Date	: 10-2028	AR. No.	: NFP/2501726
Date of Analysis	: 26-11-2025	Date of Release	: 02-12-2025

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S. No.	Tests	Specifications	Results
1.	Description	A White or off white colour round shaped biconvex scored on one side and plain on another side having each film coated tablets.	A White or off white colour round shaped biconvex scored on one side and plain on another side having each 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	420.0 mg $\pm$ 5.0%	411.0mg
6.	Uniformity of Weight	$\pm$ 5.0% of average weight	-2.16% to + 2.34%
7.	Dissolution	NLT 80%(Q)dissolved in 20 minutes	84.27% to 89.43 %
8.	Related compounds		
9.	Irbesartan related compound A	NMT 0.2%	Not detected
10.	Individual impurity	NMT 0.2%	Not detected
11.	Total impurity	NMT 0.5%	Not detected
12.	NDMA,NDEA y NMBA		
13.	NDEA-N- Nitrosodiethylamine	NMT 0.088 ppm	Not detected
14.	NDMA-N- Nitrosodiethylamine	NMT 0.32ppm	Not detected

Particulars	Prepared By	Checked By	Approved By
Name	Saloni	Hasib Ansari	Bhaskar Shinagare
Designation	Officer QC	Sr.Officer QC	Manager QC
Sign & Date			



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15.	NMBA-Acid-N-Nitroso-N-Methylamino Butyric	NMT 0.32ppm	Not detected
16.	Assay	90.0% to 110% of label claim.	98.67%W/W
17.	Microbiological count		
	Aerobic bacterial count	NMT 10 ³ /1g	35 CFU/g
	yeast& fungal count	NMT 10 ³ /1g	NIL
	E.coli,Salmonella etc	Absent/ml	Absent/ml
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 ⁰ C.	
20.	Shelf Life	3 years from the date of manufacturing.	

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