SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	Azilsartan Kamedoxomil IP	**CAS No:**	863031-24-7
Batch No.	2605001	**Manufactured by**	-Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	**Date of Analysis**	20/05/2026
Batch Quantity		**Retest Date**	APR2031

Sr No	Test	Acceptance Criteria	Results
1	Description	A white to off white powder.	Off white powder
2	Solubility	.Practically insoluble in water, sparingly soluble in methanol and slightly soluble in N, N dimethylformamide.	Complies
3	Identification – By IR	The obtained sample spectrum of Azilsartan Kamedoxomil should compare with that of the Azilsartan Kamedoxomil RS/WS.	Complies
4	Identification – By HPLC	The retention of the major peak in the chromatogram of test solution should match with that in chromatogram of standard solution, obtained in the Assay by HPLC.	Complies
5	Potassium Content	Between 6.0 to 7.0.	6.32
6	Related substances by HPLC– Impurity A	Not more than 0.15	Not Detected
7	Related substances by HPLC– Impurity B	Not more than 0.3	0.08
8	Related substances by HPLC – Impurity C	Not more than 0.15	0.01
9	Related substances by HPLC – Impurity D	Not more than 0.15	0.02
10	Related substances by HPLC – Impurity E	Not more than 0.15	Not Detected
11	Related substances by HPLC – Impurity F	Not more than 0.15	Not Detected
12	Related substances by HPLC – Impurity G	Not more than 0.15	Not Detected
13	Related substances by HPLC – Impurity H	Not more than 0.15	Not Detected
14	Any other secondary impurity	Not more than 0.1	0.02
15	Total Impurity	Not more than 1	0.1
16	Heavy metals (ppm)	Less than 20	Complies
17	Water Content (%, w/w)	Not more than 0.8	0.31

Sr No	Test	Acceptance Criteria	Results
18	Assay by HPLC (on dried basis) (%, w/w)	Not less than 98.0 and not more than 102.0	99.1
19	Related Substances by HPLC (%, w/w) Methanol	Not more than 3000 ppm	
20	Related Substances by HPLC (%, w/w) Acetone	Not more than 5000 ppm	Not Detected
21	Related Substances by HPLC (%, w/w) Dichloromethane	Not more than 600 ppm	Not Detected
22	Related Substances by HPLC (%, w/w) Diisopropylamine	Not more than 1000 ppm	Not Detected
23	Related Substances by HPLC (%, w/w) Triethylamine	Not more than 5000 ppm	Not Detected
24	Related Substances by HPLC (%, w/w) Toluene	Not more than 890 ppm	Not Detected
25	Related Substances by HPLC (%, w/w) Dimethyl sulfoxide	Not more than 5000 ppm	Not Detected
26	Related Substances by HPLC (%, w/w) Dimethyl acetamide	Not more than 1090 ppm	Not Detected
27	TAMC&TYMC a) Total Aerobic Microbial Count	NMT 1000 CFU/g	Complies
28	b) Total Combined Yeasts and Molds Count	NMT 100 CFU/g	Complies
29	Tests for Specified Pathogens Escherichia coli	Should be absent	Absent
30	Tests for Specified Pathogens Salmonella species	Should be absent	Absent
31	Tests for Specified Pathogens Staphylococcus aureus	Should be absent	Absent
32	Tests for Specified Pathogens Pseudomonas aeruginosa	Should be absent	Absent

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By	Checked by	Approved By
Sonali Nirmal Date: 23/05/2026	Dadarao Kakde Date: 23/05/2026	Nayna Nehete Date: 23/05/2026

Swapnroop Drugs And Pharmaceuticals Quality Assurance Aurangabad