

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

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CERTIFICATE OF ANALYSIS

Product : Oxcarbazepine

Batch No. : F-NOXC250504-1M3

Quantity : 150kg

Specification: USP2024

Mfg. date: 2025.05.11

Retest date: 2028.05.10

Item	Specifications	Results
Description	Light orange to creamish white or off-white powder	Off-white powder
Solubility	Soluble in acetic acid; sparingly soluble in chloroform; practically insoluble in water.	Meet the requirements
Identification	A: Comparison: Oxcarbazepine CRS.	Sample spectrum is similar to that of reference standard.
	B: The retention time of the major peak in the sample solution corresponds to that chromatogram of the standard solution, as obtained in the Assay.	The retention time of the major peak in the sample solution corresponds to that of chromatogram of the standard solution, as obtained in the Assay.
Water determination	$\leq 0.5\%$	0.12%
Related substances	Carbamazepine $\leq 0.5\%$	0.01%
	Oxcarbazepine related compound E $\leq 0.05\%$	Not detected
	Methoxycarbamazepine $\leq 0.05\%$	0.02%
	Carbamazepine related compound B $\leq 0.05\%$	Not detected
	Methoxydibenzazepine $\leq 0.05\%$	Not detected
	Any individual unspecified impurity $\leq 0.05\%$	Not detected
	Total impurities $\leq 1.0\%$	0.02%
Residual Solvents	Methanol $\leq 3000\text{ppm}$	Not detected
	Ethanol $\leq 5000\text{ppm}$	Not detected
	Methylene chloride $\leq 600\text{ppm}$	58ppm
	Chloroform $\leq 60\text{ppm}$	Not detected
	Toluene $\leq 890\text{ppm}$	Not detected
Residue on ignition	$\leq 0.1\%$	0.08%
Assay	98.0~102.0 %	99.7%
Particle Size	90% $\leq 10\mu\text{m}$	6.0 μm

Conclusion: Complies with the requirements of USP2024

Q.C. director:

吴海微

QP:

江华

Date:

2025.05.30

Date:

2025.05.30



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