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CERTIFICATE OF ANALYSIS

Product Name:	**Olmesartan Medoxomil**		
Batch No.	D5467-22-002		
Batch Type	Commercial	**Batch Size**	255.58kg
Retest Date	July, 2027	**Report Date**	August 23, 2022
Manufacturing Date	August 10, 2022	**Reference**	USP

Analytical Results

Items	**Specifications**	**Results**
Description	White or almost white, crystalline powder	White crystalline powder
Identification	1) The infrared absorption spectrum is concordant with the spectrum obtained with Olmesartan Medoxomil RS.	Conform
	2) The retention time of the major peak in the chromatogram of the Test solution corresponds to that in the chromatogram of the Reference solution, as obtained in the Assay.	Conform
Water	≤0.5%	0.1%
Residue on ignition	≤0.1%	<0.1%
Related substances (HPLC)	Olmesartan ≤0.4%	0.05%
	Olmesartan medoxomi related compound A ≤0.10%	<LOD(LOD:0.01%)
	Olefinic impurity ≤0.3%	<LOD(LOD:0.02%)
	N-alkyl impurity ≤0.10%	<LOD(LOD:0.02%)
	Ethyl-Olmesartan Medoxomi ≤0.10%	<LOQ(LOQ:0.05%)
	Any other individual unidentified impurities ≤0.10%	0.05%
	Total unidentified impurities ≤0.3%	0.05%
	Total impurities ≤0.7%	0.10%
Assay (HPLC)	98.5%~101.5% (on anhydrous and solvent-free basis)	99.9%
Residual solvents (GC)	Ethanol ≤5000ppm	<LOD(LOD:30ppm)
	Acetic acid ≤5000ppm	<LOQ(LOQ:54ppm)
	Toluene ≤890ppm	<LOD(LOD:27ppm)
	Acetone ≤5000ppm	1160ppm
	Ethyl acetate ≤5000ppm	<LOD(LOD:30ppm)
Storage Condition	Preserved in well-closed containers	
Conclusion	Complies with USP	

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Inspector: Carlifor Wu Verifier: Jack He