

Glenmark Pharmaceuticals Ltd.

Plot No. 3109, GIDC Industrial Estate,
Ankleshwar, 393002, Gujarat, India.
Tel : 02646-222265/69
Fax : 02646-222191

**QUALITY ASSURANCE DEPARTMENT
CERTIFICATE OF ANALYSIS**

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Product : OLMESARTAN MEDOXOMIL USP**Specification No** : SPC-I200-001387/2.0**SAP Code** : SA00303**Batch. No.** : 801800174**Insp. Lot No.** : 890000050876**Reference** : USP + INHOUSE**Date of Mfg.** : 14.01.2018**Re-test Date** : 13.01.2022**Date of Report** : 02.04.2018

TEST	LIMIT	OBSERVATION
Description	White to off-white crystalline powder	White crystalline powder
Solubility		
In Methanol	Sparingly soluble	Sparingly soluble
In Water	Practically Insoluble	Insoluble
Identification		
By IR	The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from USP Olmesartan medoxomil RS / working standard.	Complies
By HPLC	The ratio of the retention time of the major peak of that of the internal standard of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
Water Content	Not more than 0.5%w/w	0.08 %w/w
Residue on ignition	Not more than 0.1%w/w	0.05 %w/w
Heavy metals	Not more than 10 ppm	Less than 10 ppm
Organic impurities (By HPLC)		
Olmesartan i.e. 1-([2'-1H-Tetrazol-5-yl]biphenyl-4-yl)methyl-4-(2-hydroxypropan-2-yl)-2-propyl-1H-imidazole-5-carboxylic acid.	Not more than 0.5%	Below disregard limit
Olmesartan medoxomil related compound A i.e. 1-([2'-1H-Tetrazol-5-yl]biphenyl-4-yl)methyl-4,4-dimethyl-2-propyl-1H-furo[3,4-d]imidazol-6(4H)-one	Not more than 0.1%	Below disregard limit
Olefinic impurity i.e. (5-Methyl-2-oxo-1,3-dioxol-4-yl)methyl 1-((2'-1H-tetrazol-5-yl)biphenyl-4-	Not more than 0.6%	Not detected

Prepared By : Janak Gondaliya
Designation : Officer
Date : 01.04.2018

Approved By : Jitendra Ramani
Designation : Assistant Manager
Date : 02.04.2018

Printed Date : 02.04.2018**Copy No.** : 1

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Registered Office : B/2, Mahalakshmi chambers, 22 Bhulabhai Desai Road, Mumbai 400026.

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TEST	LIMIT	OBSERVATION
yl)methyl)-4-(prop-1-en-2yl)-2-propyl-1H-imidazole-5-carboxylate		
N-alkyl impurity i.e. (5-Methyl-2-oxo-1,3-dioxol-4-yl) methyl 4-(2-hydroxypropan-2-yl)-2-propyl-1-((2'-(2-trityl-2H-tetrazol-5-yl) biphenyl-4-yl) methyl)-1H-imidazole-5-carboxylate	Not more than 0.1%	Not detected
Any other individual unidentified impurity	Not more than 0.10%	0.09 %
Total impurities	Not more than 1.3%	0.09 %
Assay By HPLC (On anhydrous basis and solvent-free basis)	Not less than 98.5% and Not more than 101.5% w/w	99.6 %w/w
Inhouse tests		
Residual Solvents (By GC)		
Acetone	Not more than 5000 ppm	1563 ppm
Ethylacetate	Not more than 5000 ppm	241 ppm
Isopropyl alcohol	Not more than 5000 ppm	6 ppm
Methylene Chloride	Not more than 600 ppm	Not detected
Toluene	Not more than 890 ppm	Not detected
Tetrahydrofuran	Not more than 720 ppm	1 ppm
Polymorphic identification (By XRD)	The X-Ray diffractogram of substance being examined should exhibit characteristic 2theta values at 9.2, 12.6, 12.8, 18.6 and 23.3 $\pm$ 0.2°.	The X-Ray diffractogram of substance is examined which exhibit characteristic 2theta values at 9.2, 12.7, 12.9, 18.6 and 23.4°.
Particle size (By Malvern)		
D(90)	Less than 30 μ m	5.3 μ m

For Organic impurities : Disregard any peak below 0.05%

Storage Condition :

Preserve in well closed container, protected from moisture , and store below 25°C.

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