

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**Specification No** : SPC-I200-002180/1.0**SAP Code** : SD01401**Batch. No.** : 80151320**Insp. Lot No.** : 890000002487**Reference** : USP + INHOUSE**Date of Mfg.** : 29.06.2015**Retest Date** : 08.06.2019**Date of Report** : 03.07.2015

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	0.13 %w/w
Residue on ignition	Not more than 0.1 %w/w	0.03 %w/w
Heavy metals	Not more than 10 ppm	Less than 10ppm
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%	0.20 %
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%	Below disregard limit

Prepared By : Prashant Vaidya**Designation** : Sr. Executive**Date** : 03.07.2015**Approved By** : Rajneesh Jain**Designation** : Manager**Date** : 03.07.2015**Printed Date** : 03.07.2015**Copy No.** : 1**This is electronically signed document, hence need not to be signed.****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-2-yl)-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-1H-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%	0.05 %
Total impurities	Not more than 1.3%	0.23 %
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	938 ppm
Ethyl acetate	Not more than 5000 ppm	Not detected
Isopropyl alcohol	Not more than 5000 ppm	Not detected
Methylene Chloride	Not more than 600 ppm	Not detected
Toluene	Not more than 890 ppm	1 ppm
Tetrahydrofuran	Not more than 720 ppm	Not detected
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 being examined exhibit characteristic 2theta values at 9.2, 12.7, 12.9, 18.6 and 23.4°.
Particle size (By Malvern)		
D(90)	Less than 30µm	6.5 µm
For Organic impurities : Disregard any peak below 0.05%		
Storage Condition :		

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Reference : USP + INHOUSE

Date of Mfg. : 29.06.2015

Retest Date : 08.06.2019

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Store in well-closed container at 25°C with excursions permitted between 15°C and 30°C

Remark : The product complies as per above specification

Prepared By : Prashant Vaidya

Designation : Sr. Executive

Date : 03.07.2015

Approved By : Rajneesh Jain

Designation : Manager

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