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

glenmark
A new way for a new world

QUALITY ASSURANCE DEPARTMENT
CERTIFICATE OF ANALYSIS

Product : OLMESARTAN MEDOXOMIL

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

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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-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 ± 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 :

Prepared By	: Prashant Vaidya	**Approved By**	: Rajneesh Jain
Designation	: Sr. Executive	**Designation**	: Manager
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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

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Designation	: Sr. Executive	**Designation**	: Manager
Date	: 03.07.2015	**Date**	: 03.07.2015

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Ipca Laboratories Limited

P.O. SEJAVTA 457 002, DIST. RATLAM (M. P.)

ipca

QUALITY DIVISION
CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : HYDROCHLOROTHIAZIDE Ph. Eur.

BATCH SIZE	: 479.0 Kgs	BATCH No.	: 3105HCRII
MFG. DATE	: May. 2013	A. R. No.	: IBD - 131709
RETEST DATE	: Apr. 2018	DATE	: 08/06/2013

TESTS	SPECIFICATIONS	RESULTS
CHARACTERS	A white or almost white, crystalline powder, very slightly soluble in water, soluble in acetone, sparingly soluble in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides.	Conforms
IDENTIFICATION	The infrared absorption spectrum of sample and standard are concordant.	Conforms
ACIDITY OR ALKALINITY	The solution is yellow. NMT 0.4 ml of 0.01M hydrochloric acid is required to change the colour of the indicator to red.	Conforms
RELATED SUBSTANCES (By HPLC)	4-Amino-6-Chloro-1,3-Benzenedisulfonamide [Impurity B] : NMT 0.50%	< 0.05%
	6-chloro-N-[(6-chloro-7-sulphamoyl-2,3-dihydro-4H-1,2,4-benzothiadiazin-4-yl 1,1-dioxide)methyl]-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulphonamide 1,1-dioxide [Impurity C] : NMT 0.50%	< 0.05%
	Chlorothiazide [Impurity A] : NMT 0.50%	< 0.05%
	Any Unspecified Impurity : NMT 0.10%	< 0.05%
	Sum of all Impurities : NMT 1.0%	< 0.05%
CHLORIDES	NMT 100 ppm	< 100 ppm
LOSS ON DRYING (at 105°C)	NMT 0.5% w/w	0.28% w/w
SULPHATED ASH	NMT 0.1% w/w	0.08% w/w
ASSAY (By HPLC)	97.5% - 102.0% of $C_7H_8ClN_3O_4S_2$ (on dried basis)	99.4% (udb)
PARTICLE SIZE (By Malvern)	90% Between 30 - 70 µm	66 µm

REMARKS : The above sample CONFORMS as per Ph. Eur. specifications.

ANALYST
DATE : 01/11/2013

MANAGER QUALITY CONTROL
DATE OF PRINT : 01/11/2013