



Divi's Laboratories Limited

CERTIFICATE OF ANALYSIS

PRODUCT	Losartan Potassium
DATE OF MANUFACTURE	Oct 2012
RETEST DATE	Mar 2014
BATCH NUMBER	2-MS-0041012
BATCH SIZE	789 kg

Test	Specification	Result
Characteristics	White to off-white free flowing crystalline powder	Off-white free flowing crystalline powder. Free from visible evidence of contamination.
Assay (HPLC, USP)	98.5-101.0% (water and residual solvent free)	99.7
Assay (titration, EP)	98.5-101.5%(dried substance)	99.8
Chromatographic Purity (USP)	Any Individual Identified Impurity: Maximum 0.2%	<0.05%
	Any Individual Unidentified Impurity: Maximum 0.1%	<0.05%
	Total Impurities: Maximum 0.5%	<0.05%
Chromatographic Purity (EP)	Compound E: Maximum 0.15%	<0.05%
	Compound F: Maximum 0.15%	<0.05%
	Any Unspecified Impurity: Maximum 0.10%	<0.05%
	Total Impurities: Maximum 0.3%	<0.05%
Heavy Metals (USP)	Maximum 0.001%	Conform
Heavy Metals (EP)	Maximum 20 ppm	Conform
Identity (IR) LosartanPotassium (USP, EP)	The sample spectrum exhibits maxima only at the same wavelengths as those of an authentic specimen of Losartan Potassium similarly treated	Conform
Identity (UV) Losartan Potassium (USP)	The sample spectrum exhibits maxima only at the same wavelengths as those of the standard. The respective absorptivities do not differ by more than 3.0%	Conform
Identity Potassium (flame test, USP)	The sample imparts a violet color to a non-luminous flame	Conform
Identity Potassium (precipitate, EP)	A: No precipitate is formed B: No precipitate is formed C: A white crystalline precipitate is formed	Conform

**"An ISO-9001 (QMS); ISO-14001 (EMS) and OHSAS-18001 (Health & Safety)
Triple Certified Company"**

FACTORY : Unit-2, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh - 531 162, INDIA.
Ph. :+91-8922-248911, Fax :+91-8922-248922
CORPORATE OFFICE: Divi Towers, 7-1-77/E/1/303, Dharam Karan Road, Anaparthi, Hyderabad - 500 016, INDIA. CIN: L24110AP1990PLC011854
Ph. :+91-40-23786300, 23786400, Fax :+91-40-23786460, E-mail :mail@divislaboratories.com, Website :www.divislaboratories.com



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Test	Specification	Result
Residual Solvents (GC)	Total (Cyclohexane + 2-Propanol): Max. 0.3%	0.0
Water (KF, USP)	Maximum 0.5%	0.3
Loss on Drying (EP)	Maximum 0.5%	0.2
Clarity of Solution	Maximum 5 NTU	1
Color of Solution	Maximum 10	4
Bulk Density	Loose 0.33-0.52g/ml	0.37
Particle size	MV 19-92 μ m	48
	d ₁₀ 8-39 μ m	19
	D ₉₀ 41-146 μ m	83

Prepared by:

P. ROSAIAH
Sr. Analyst

Date: 25/07/2014

Approved by:

K. Srikanth
Sr. Manager

Date: 25/07/2014

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