
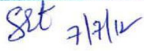



TYPICAL CERTIFICATE OF ANALYSIS

Product Name	LOSARTAN POTASSIUM, USP	A.R Number	AR/FP/LPB/12/0018
Batch Number	LPB/12/018	Date of Release	07/07/2012
Mfg. Date	May – 2012	Retest Date	Apr-2015
Qty	300.00 Kg	Ref STP No.	STP/FP/LP/001/01

S. No.	Test	Specification	Result
1.	Description	A White to off white color powder	An off white color powder
2.	Solubility	Freely soluble in water, soluble in isopropyl alcohol, Slightly soluble in acetonitrile	Complies
3.	Identification		
	A) By IR	The IR spectrum obtained from the test sample should match with the IR spectrum obtained from the Working Standard.	Complies
	B) By UV	The UV absorption spectra of the standard solution and the test solution exhibit maxima and minima at the same wave lengths	Complies
	C) Potassium test	A white crystalline precipitate should be produced on addition of Sodium bitartrate TS in neutral conditions, which is soluble in solutions of Alkali hydroxides	Complies
4.	Water Content by KF (%w/w)	Not more than 0.5% w/w	0.38
5.	Heavy Metals	Not more than 0.001%	Less than 0.001
6.	Limit of Cyclohexane and Isopropyl alcohol		
	Cyclohexane	Not more than 0.1%	Not Detected
	Isopropyl alcohol	Not more than 0.2%	Not Detected
7.	Chromatographic purity by HPLC		
	Any individual impurity	Not more than 0.2 %	0.07
	Total impurities	Not more than 0.5 %	0.20

APPROVED

 07.07.2012	 SRT 7/7/12	 07/07/2012
Prepared by & Date	Checked by & Date	Approved by & Date


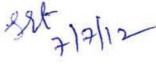
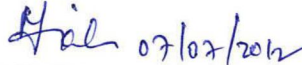
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S. No.	Test	Specification	Result
8.	Assay by HPLC (On Anhydrous solvent free basis)	Not less than 98.5% and Not more than 101.0%	99.76
9.	*Residual solvents by GC		
	Toluene	Not more than 890 ppm	Not detected
	Chloroform	Not more than 60 ppm	Not detected
	Methanol	Not more than 300 ppm	Not detected
	Ethyl Acetate	Not more than 5000 ppm	Not detected
	Acetone	Not more than 5000 ppm	110 ppm

* Additional tests

REMARKS: The product complies as per above specification.

APPROVED

 07.07.2012	 7/7/12	 07/07/2012
Prepared by & Date	Checked by & Date	Approved by & Date