

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : KD -634	A.R.NO : FPC / 183 / 11
Name of Product : Amlodipine Besilate BP	Released Date : 17 /11 / 2011
Batch No. : AMB / 06 / 11	Mfg. Date : NOV - 2011
Batch Qty. : 90.00 KGS	Exp. Date : OCT - 2016

Sr. No.	Test	Specification	Results
1	Appearance	White or almost White Powder	Almost White Powder
2	Solubility	Slightly soluble in water, freely soluble in methanol, sparingly soluble in anhydrous ethanol, slightly soluble in 2-propanol.	Slightly soluble in water, freely soluble in methanol, sparingly soluble in anhydrous ethanol, slightly soluble in 2-propanol.
3	Identification: By Infrared absorption spectrophotometry	Infrared absorption spectrum of the sample concordant with that of standard	Infrared absorption spectrum of the sample concordant with standard
4	Optical Rotation	- 0.10° to + 0.10°.	0 °
5	Related Substance (By HPLC) Impurity D Impurity A Impurity E Impurity F Unspecified Impurity Total Impurity	 Not more than 0.3% Not more than 0.15% Not more than 0.15% Not more than 0.15% Not more than 0.1% Not more than 0.8%	 Not Detected Not Detected Not Detected 0.039 % 0.008 % 0.052 %
6	Water	Not more than 0.5 %	0.17 %
7	Sulphated Ash	Not more than 0.2 %	0.04%
8	Assay (By HPLC)	97.0 % - 102 %	99.90 %

Remark: The material complies as per BP 2010 standards.

Analysed By
Q.C. Officer

Approved By
Q.A. Manager