



KERALA STATE DRUGS AND PHARMACEUTICALS LTD,
KALAVOOR PO, ALAPPUZHA, KERALA-688522

Raw Material Specification

Name of the Material: AMLODIPINE BESYLATE I.P.			
SOP No:	KSDP/SOP/SPEC01	Spec. No:	KSDP/R/SPEC01/12
Effective date:	01/12/2022	Revision No:	01

Sl.No.	TESTS	SPECIFICATION
1	Description	A white or almost white powder
2	Identification	A. By TLC B. By IR Absorption spectrophotometer C. By UV absorption maximum at about 360nm, the specific absorbance at the maximum is 113 to 121.
3	Optical rotation	-0.10° to +0.10°, determined in a 1.0%w/v solution in methanol
4	Related substances (by TLC & HPLC)	Complies I.P.
5	Sulphated ash	Not more than 0.2%w/w
6	Water	Not more than 0.5%, determined on 3.0g
7	Assay *(by HPLC)	Not less than 98 % w/w to 102 %w/w, calculated on the anhydrous basis

*In House Specification

The product complies to I.P. 2022 with respect to above tests.

Prepared by	Checked by	Reviewed By	Approved By	MASTER COPY UNCONTROLLED COPY
Officer QA	QC Head	Production Head	QA Head	
01/12/22	01/12/22	01/12/22	01/12/22	