

WRS
AGS-1



astra lifecare
(India) Pvt. Ltd.

Certificate of Analysis
Working Standard

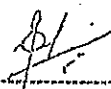
Name of the Raw Material : Amlodipine Besylate USP
W/S No. : QC/WS/071
Date of Preparation : 17.09.15
Use Before : 16.09.16
Evaluated against USPRS : Lot No.: H01102

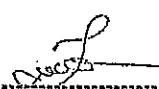
Sr. No.	Test	Result	Specification
1.	Description	Almost white Powder.	White or almost white powder.
2.	Identification : IR	The IR absorption spectrum of substance is concordant with the reference spectrum of Amlodipine besylate RS.	The IR absorption spectrum of substance should be concordant with the reference spectrum of Amlodipine besylate CRS.
3.	Related Compounds Test 1: TLC Test 2: HPLC Impurity A Total other Impurities	No secondary spot observed in sample solution. Not detected 0.077 %	Any spot obtained from the test solution, except for the principal spot, should not greater in size than the spot obtained from standard solution 1 (0.3 %). At most two spots should more intense than the spot obtained from standard solution 2 (0.1 %). Not more than 0.3 % Not more than 0.3 %
4.	* Water	0.0933 %	Not more than 0.5 %
5.	* Assay	99.31 %	Between 97.0 % and 102.0 % on anhydrous substances.
6.	* Polency	99.21 %	---

* Average Result of Triplicate Analysis.

Conclusion: The sample complies with the specification.

Issued on: 17/09/15


Prepared By


Q.C. Manager

