

WR S
A53-1

CERTIFICATE OF ANALYSIS
(Working Standard)

Name of the sample	AMLODIPINE BESILATE BP		
Lot Number	WS/A-01.18		
Date of analysis	Jul 30, 2015	Date of retest	Jul 29, 2016

Sr. No.	Test(s)	Specification(s)	Result(s)
1.0	Description	White or almost white powder.	Almost white powder Complies
2.0	Solubility	Slightly soluble in water, freely soluble in methanol, sparingly soluble in anhydrous ethanol, slightly soluble in 2-propanol	Complies
3.0	Identification By IR	The infrared absorption spectrum of the substances being examined in mulls should be concordant with the spectrum obtained from Amlodipine Besylate working standard.	Positive
4.0	Optical rotation at 589 nm (1% solution in methanol)	Between - 0.10° and + 0.10°	+0.007° Positive
5.0	Related substances		
i)	Impurity D	Not more than 0.30%	0.002%
ii)	Impurity A	Not more than 0.15%	Not detected
iii)	Impurity B	Not more than 0.15%	Not detected
iv)	Impurity F	Not more than 0.15%	0.004%
v)	Unspecified impurity	Not more than 0.10%	0.005%
vi)	Total impurities	Not more than 0.80%	0.014%
6.0	Water content	Not more than 0.5% w/w	0.08%
7.0	Assay	Not less than 97.0% w/w and not more than 102.0% w/w of $C_{26}H_{31}ClN_2O_8S$, on an anhydrous basis.	97.9% (on as is basis) 98.0% (on anhydrous basis)

Remarks: The working standard of Amlodipine Besilate WS/A-01.18, evaluated against reference standard Batch 4.1, complies as per BP specification.

Prepared By Smita Musale Analyst <i>S.S. Musale</i> Date: Jul 30, 2015	Checked By Nitin Gonjare Executive <i>N. Gonjare</i> Date: Jul 30, 2015	Approved By Govind Morajkar Manager <i>G. Morajkar</i> Date: Jul 30, 2015
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