

MYLAN LABORATORIES LIMITED F-4 & F-12, Malegaon MIDC, Sinnar, Nashik - 422 113, Maharashtra, India.

CERTIFICATE OF ANALYSIS (WORKING STANDARD)

Name: Atazanavir Sulfate		IW.S. A.R. No.	MLNWSD16000192
Source Batch No.	50066131		
Date Of Standardization	Dec 21 2016 4:47PM	Standardized against	Atazanavir Sulfate USPRS Lot No.: F020D0
Storage Condition	2-8°C	Validity	Dec 15, 2017
STP No.	RMPATS019-11	Ref. Specification	RMSATS019-12

S. No.	TEST	SPECIFICATION	RESULTS
1	Description	White to pale yellow powder which may contains lumps.	Pale yellow powder.
2	Identification (By Infrared Absorption)	The absorption maxima in the spectrum obtained with the substance to be examined corresponds in position and relative intensity to those in the spectrum obtained with the working standard.	The absorption maxima in the spectrum obtained with the substance corresponds in position and relative intensity to those in the spectrum obtained with the Atazanavir Sulfate USPRS Lot No. F020D0.
3	Water (By KF)	Not more than 1.0% w/w	0.10 % w/w
4	Assay (By HPLC)		
4.1	Assay on 'as is basis'	Not less than 83.5% w/w and not more than 91.0% w/w.	88.4 % w/w
4.2	On corrected for water and sulfuric acid	Not less than 97.5% w/w and not more than 102.0% w/w.	100.5 % w/w
4.3	On corrected for water, residual solvents and sulfuric acid	Not less than 98.0% w/w and not more than 102.0% w/w.	100.5 % w/w



Olympia d By	iBhushan.Amrutkar		Approved By		Gautam.Patil
Checked By		2016 5:52PM	Approved On		Dec 21 2016 4:47PM
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