

F18-2

F18-2



QUALITY ASSURANCE DEPARTMENT
WORKING STANDARD- CERTIFICATE OF ANALYSIS

Product Name	EVEROLIMUS - WORKING STANDARD		
Batch No.	BD/EV/WS/16/01	A.R.No.	BD/EV/WS/COA/16/01/01
Date of Analysis	16/04/2016	Date of Issue	16/04/2016
Mfg. Date	Apr 2016	Retest Date	15/04/2017
Exp. Date	Mar 2019	Primary Working Std. No.	BDR/PWS/EV/16/01
Storage	Store in tight container between 2°C to 8°C, protected from light.		

**B
D
R
P
H
A
R
M
A
C
E
U
T
I
C
A
L
S
I
N
T
E
R
N
A
T
I
O
N
A
L
P
V
T.
L
T
D.**

S.No.	TEST	STANDARD	RESULT
1.	Description	White to off white powder	White powder
2.	Identification <ul style="list-style-type: none"> By IR By HPLC 	<p>Infrared spectra of the test sample in KBr must be concordant with that of a similar preparation of Everolimus Working standard.</p> <p>The retention time of the principal peak in the chromatogram of the sample corresponds to the principal peak in the chromatogram of the working standard as obtained under the test for assay</p>	<p>Complies</p> <p>Complies</p>
3.	Water content (by KF)	Not more than 2.0%	1.2 %
4.	Assay of (By HPLC) (on anhydrous substance)	Between 96% to 102%	99.7 %
5.	Potency	For information only	98.5 %

Remarks: The sample complies /does not comply as per above In-House Specification.



PREPARED BY Parth Thakkar QA Officer	Checked By: QC Manager Rakshit Chokshi	Approved By: QA Manager Deepak Suthiar
--	--	--