

QUALITY ASSURANCE DEPARTMENT
WORKING STANDARD- CERTIFICATE OF ANALYSIS

Product Name	GEFITINIB – WORKING STANDARD		
Batch No.	BD/GF/WS/16/01	A.R.No.	BD/WS/GFZN140008/01
Date of Analysis	20/01/2016	Date of Issue	22/01/2016
Mfg. Date	Jan-2016	Retest Date	21/01/2017
Exp. Date	Dec-2019	Primary Working Std. No.	GF/WS/15/01
Storage	Store protect from light and moisture, at a temperature not exceeding 25°C.		

S.No.	TEST	STANDARD	RESULT
1.	Description	White to off white crystalline powder	Off white crystalline powder.
2.	Identification	The IR Spectrum of sample should concordant with similar preparation of that of Gefitinib working standard.	Complies
3.	Loss on drying	NMT 1.0% w/w	0.1%
4.	Assay (On dried basis)	NLT 98.0% and NMT 102.0%	99.95%
5.	Potency	For information	99.85 %

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



PREPARED BY QA Officer Nilam Parikh <i>22/01/2016</i>	Checked By: QC Manager Rakshit Choksi <i>22/01/2016</i>	Approved By: QA Manager Deepak Suthar <i>22/01/2016</i>
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