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QUALITY ASSURANCE DEPARTMENT WORKING STANDARD- CERTIFICATE OF ANALYSIS

Product Name	ABIRATERONE ACETATE- WORKING STANDARD		
Batch No.	BD/AR/WS/16/01	A.R.No.	BD/AR/WS/COA/16/01/01
Date of Analysis	20/01/2016	Date of Issue	22/01/2016
Mfg. Date	Jan-2016	Retest Date	21/01/2017
Exp. Date	Dec-2018	Primary Working Std. No.	BDR/WS/AR/15/01
Storage	Store below 25°C.	¥	

S.No.	TEST	STANDARD	RESULT
1.	Description	White to Off white crystalline powder	White Crystalline powder.
2.	Identification		
8 1	A) By HPLC:	The retention time of the	The retention time of the
	. (6)	major peak in the	major peak in the
	12	chromatogram of sample	chromatogram of sample
		corresponds to that in the	corresponds to that in the
		chromatogram of Standard	chromatogram of Standard
		preparation	preparation
B) E	B) By IR:	The IR spectrum of sample is	The IR spectrum of sample is
	2 B	in accordance with that of	in accordance with that of
		reference standard	reference standard
3.	Water	NMT 1.0 %	0.08%
4.	Assay by HPLC	NLT 97.0% and NMT	99.93 %
	(On anhydrous basis)	102.0%	
5.	Potency	For information	99.85 %

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



PREPARED BY

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