

QUALITY ASSURANCE DEPARTMENT
WORKING STANDARD- CERTIFICATE OF ANALYSIS



BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD.

Product Name	TEMOZOLOMIDE USP- WORKING STANDARD		
Batch No.	BD/TZ/WS/16/01	A.R.No.	BD/TZ/WS/COA/16/01/01
Date of Analysis	18/01/2016	Date of Issue	19/01/2016
Mfg. Date	Jan-2016	Retest Date	18/01/2017
Exp. Date	Dec-2019	Reference Std. No.	HOM330
Storage	Preserve in well-closed containers, and store at room temperature.		

S.No.	TEST	STANDARD	RESULT
1.	Description	White to light pink/light tan powder	White powder
2.	Identification A) By IR: B) By HPLC:	The IR spectrum of sample is in accordance with that of reference standard. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	The IR spectrum of sample is in accordance with that of reference standard. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
3.	Water Determination	NMT 0.4 %	0.10%
4.	Assay (On as-is basis)	NLT 98.0% and NMT 102.0%	99.54%
5.	Potency	For information	99.44 %

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



Prepared By: QA Officer Bhavdip Jesadiya	Checked By: QC Manager Rakshit Choksi	Approved By: QA Manager Deepak Suthar
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