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QUALITY ASSURANCE DEPARTMENT WORKING STANDARD- CERTIFICATE OF ANALYSIS

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.	H0M330
Storage	Preserve in well-closed containers, and store at room temperature.		

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

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





Prepared By:	Checked By:	Approved By
QA Officer Phandin Logadina 19/01/2016	QC Manager 19 12 201	QA Managor
Bhavdip Jesadiya 101/01/2	Rakshit Choksi	Deepak Suthan

WORKS / PLANT: R. S. No. 578, Near Effluent Channel Road. Village: Luna - 391 440. Tal. Padra. DIST. VADODARA. Telefax: +91-2662-222803/222821 HEAD OFFICE: 407/408, Sharda Chambers, 15 New Marine Lines. MUMBAI - 400 020. Phone: +91-22-40560560/1/2/3 Fax: +91 22 40560555 CITY OFFICE: A/2. 1st Floor. Gayatrikrupa Society. Opp. Iskon Heights, Near Harikrupa Society, Gotri Road. Gotri, Vadodara - 390 021. Phone: +91-265-2371232