

CENTURY

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PHARMACEUTICALS LTD.

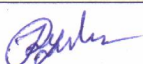
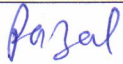

Drug Manufacturing License No: G/250 & G/513 Dt.29/1/96
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QUALITY ASSURANCE CERTIFICATE OF ANALYSIS

B. NO: 09824001-OH	NAME OF PRODUCT	A. R. NO: OH/20/001/09824
MFG DATE: May 2020	OXYTETRACYCLINE HYDROCHLORIDE EP(Injectable)	
EXP DATE: April 2024		CAS NO: 2058-46-0
TESTING DATE: 14/05/2020		RELEASE DATE: 16/05/2020

SR. NO	TEST	SPECIFICATION	OBSERVATION
01	Characters Appearance Solubility	Pale Yellow, crystalline powder, hygroscopic. Freely soluble in water, sparingly soluble in alcohol. Solutions in water become turbid on standing, owing to the precipitation of oxytetracycline.	Yellow, crystalline powder, hygroscopic. Complies
02	Identification	To comply the test A,B,C and D	Complies
03	pH	Between 2.3 to 2.9	2.73
04	Light-Absorbing	At 430nm NMT 0.5	0.254
	Impurities	At 490nm NMT 0.2	0.041
05	Related Substances	Impurity C. NMT 2.0 % Impurity B. NMT 1.0 % Impurity A. NMT 0.5 % Impurity D NMT 0.2% Impurity E NMT 0.2% Any other impurity NMT 0.1% Total Impurities NMT 3.5%	Complies Complies Complies Complies Complies Complies
06	Water	Not more than 2.0 %	0.68 %
07	Sulphated Ash	Not more than 0.2 %	0.029 %
08	Assay	94.5 to 102% (anhydrous substance)	99.60 %
09	Bacterial Endotoxin	NMT 0.4 IU/mg of Oxytetracycline	Complies
10	Microbial Limit Tests		
	i)Total aerobic microbial count	i)NMT 100 cfu/g	Complies
	ii)Total combined molds and yeasts count	ii)NMT 10 cfu/g	Complies

REMARK: The product complies as per EP 9.0 specifications.

	PREPARED BY	CHECKED BY	APPROVED BY
SIGNATURE			
NAME	Jyoti Yadav	Pazal Patel	Dr. Anand K. Dubey
DATE	16/05/2020	16/05/2020	16/05/2020