

PROCHEM PHARMACEUTICALS PVT. LTD

140-141, Makkanpur Bhagwanpur, Roorkee, Dist. Haridwar (UK)

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drug & Cosmetic Act 1940 and the rule there under)
Mfg. Lic. No.-78/UA/2016

REPORT No : PTT/24/1830

PRODUCT : Ofloxacin & Ornidazole Tablets IP
Healing -O2

BATCH No : THP-241830

Mfg. Date : 09/2024

Exp. Date : 08/2026

Date of Receipt : 19/09/2024

Batch Size : 5.0Lac

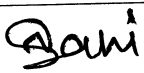
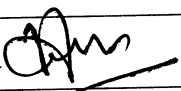
Sample Qty. : 50Tabs

Test	Specifications		Results
Description	Orange colour , elongated, biconvex, plain on both side film coated tablets.		Complies
Identification	In the Assay The principal peak in the chromatogram obtained with the test solution for Ofloxacin and Ornidazole corresponds to the peak chromatogram obtained with the reference solution.		Complies
Average Weight	840mg		850.9mg
Uniformity of Weight	± 5 % of Average weight		Min: 827.2mg (-2.78)% Max: 860.1mg (+1.08)%
Dissolution Test	Ofloxacin I.P	Q. Not less then 75percent of the stated amount of Ofloxacin & Ornidazole	(89.04 – 93.93)%
	Ornidazole I.P		(86.75 – 88.76)%
Related substances			
Imp. at RRT0.23(Ornidazole)		NMT 0.5%	BDL
Imp. at RRT0.75 (Ornidazole)		NMT 0.5%	Not Detected
Total Imp.(Ornidazole)		NMT 1.0%	0.155%
Single Max. Imp.(Ofloxacin)		NMT 1.0%	0.162%
Total Imp.(Ofloxacin)		NMT 2.0%	0.162%

Assay: Each film coated tablet contains:

Ingredients:-	Claim	Found	%of Claim	Limit
Ofloxacin IP	200mg	200.99mg	100.50%	(180-220)mg
Ornidazole IP	500mg	499.25mg	99.85%	(450-550)mg

Conclusion : In the Opinion of the under signed, the sample referred to above is of STANDARD QUALITY/NOT OF STD. QUALITY as defined in the act and the rules made there under as per IP

ANALYSE BY 	CHECKED BY 	APPROVED BY 
DATE: 25/09/2024	DATE: 25/09/2024	DATE: 25/09/2024