

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/ /

PRODUCT :

Ondansetron Orally Disintegrating Tablets IP
Ondaheal MD4

BATCH No :THP-241829

Mfg. Date : 09/2024

Exp. Date : 08/2026

Date of Receipt : 27/09/2024

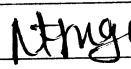
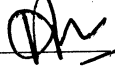
Batch Size : 5.0Lac

Sample Qty. : 50Tabs

Test	Specifications	Results
Description	White Colour, round shape, biconvex, uncoated OrallyDisintegrating tablets.	Complies
Identification	Positive test for Ondansetron HCL	Complies
Average Weight	170mg	170.36mg
Dissolution test	Q.NLT 80%	(92.25 – 97.25)%
Uniformity of Weight	± 7.5% of Average weight	Min: 167.42mg (-1.72)% Max: 173.12mg (+1.62)%
Disintegration Time	NTM -30 sec	24 Sec
Uniformity of content	Not more than one of the individual values is outside the limits 85 to 115 percent of the average value and none is outside the limits to 75 to 125 percent	Min: 97.26% Max: 106.50%
Related substances	2-Methylimidazole NMT 0.15%	Not Detected
	Ondasatron impurity D NMT 0.12%	Not Detected
	Any individual Impurity NMT 0.20%	Not Detected
	Total impurity NMT 0.5 %	Not Detected

Assay:- Each uncoated Orally disintegrating tablets contains:	Found/Tablet	Claim/Tablet	% of Claim	Limit
Ondansetron Hydrochloride IP equivalent to Ondansetron	3.992mg	4 mg	99.8%	(3.6-4.4) mg

Conclusion : In the Openion of the under signed, the sample reffered to above is of STANDARD QUALITY/~~NOT OF STD. QUALITY~~ as defined in the act and the rules made there under IP, BP, USP & I H S.

ANALYSE BY 	CHECKED BY 	APPROVED BY 
DATE: 01/10/2024	DATE: 01/10/2024	DATE: 01/10/2024