

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Ondaheal Syrup	A.R. No.	FG/G/24A0165
Generic Name	Ondansetron Oral Solution IP	Sample Quantity	14 Bottles
Batch No.	AGL40501	Sample Received on	09/05/2024
Batch Size	10,000 Bottles	Analysis Date	09/05/2024
Mfg. Date	05/2024	Release Date	15/05/2024
Exp. Date	04/2026	Page No.	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Orange colour Syrup filled in 30 ml amber colour PET bottle sealed with ROPP aluminium cap.	Orange colour Syrup filled in 30 ml amber colour PET bottle sealed with ROPP aluminium cap.
2.	Identification:		
	A. By TLC	The chromatogram obtained with the test solution corresponds to that obtained with the reference solution.	Complies
	B. By HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Weight per ml	Between 0.800 gm/ml to 1.200 gm/ml	1.0510 gm/ml
4.	pH	Between 3.3 to 4.0	3.85
5.	Average filled Volume	Not less than 30.0 ml	30.45 ml
6.	Uniformity of filled Volume	Not less than 28.5 ml	Min:- 30.0 ml Max:- 31.0 ml
7.	Assay:		
	Each 5 ml contains:	Claim	Limit
	Ondansetron Hydrochloride IP Eq. to Ondansetron	2 mg	Between 95.00 % to 105.00 % of stated amount (Between 1.90 mg to 2.10 mg)
			mg %
			1.9901 mg 99.50%
8.	Microbial Limit Tests:		
a.	Total aerobic microbial count	NMT 100 cfu/ml	25 cfu/ml
b.	Total yeast and mould count	NMT 50 cfu/ ml	Less than 10 cfu/ml
c.	Enterobacteriaceae count	NMT 10 cfu/ ml	Absent/ml
d.	Salmonella	Should be absent/ ml	Absent/ml

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Braveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	15/05/2024	15/05/2024	15/05/2024