

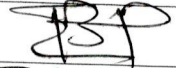


Brand Name of the Product:	<b>ELTROMBO-50</b>		
Generic Name of the Product:	ELTROMBOPAG OLAMINE TABLETS (50 mg)		
Batch No.:	ACT2303ELYA	A.R. Number:	FPACT2303ELYA
Mfg. Date:	11/2023	Date of Sampling:	16/11/2023
Exp. Date:	10/2025	Date of release:	23/11/2023
Batch Size:	8600 Tablets	Reference:	IH

S.NO	TEST	SPECIFICATION	RESULT
1.	Description	Brown colour, circular shaped biconvex, film coated tablets plain on both side.	Brown colour, circular shaped biconvex, film coated tablets plain on both side.
2.	Identification	In assay the principle peak in chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies.
3.	Average weight	430.0 mg $\pm$ 5 % (408.5 mg to 451.5 mg )	426.935 mg
4.	Uniformity of weight	Not more than 2 of the individual weights deviate from the average weight by more than 5% and none deviate by more than 10%.	-2.12% +1.35%
5.	Disintegration Test	Not more than 30 minutes	07 minutes 47 seconds
6.	Dissolution	NLT 70 % (Q)	Min: 91.90 % Max: 99.46% Mean: 96.03%

**Remarks :** In the opinion of the undersigned the sample complies / ~~does not comply~~ with the IP/BP/USP/In-House Specifications.




Analysed By		Checked By		Approved By	
Name	Gaurav Jha	Name	Dm/Git	Name	Bhanu
Date	23/11/2023	Date	23/11/2023	Date	23/11/2023

**Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala, Distt.: Solan, Himachal Pradesh - INDIA**

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7.	Assay: Each film Coated Tablet Contains:- Eltrombopag Olamine eq. to Eltrombopag 50 mg	45.0 mg to 55.0 mg (90.0 % to 110.0 %)	50.33 mg (100.66 %)
8.	Microbial Enumeration Test		
(i)	Total Aerobic Microbial Count	NMT 1000 cfu/gm	30 cfu/gm
(ii)	Total yeast and mold count	NMT 100 cfu/gm	Less than 10 cfu/gm
(iii)	E.Coli	Should be absent	Absent

**Remarks :** In the opinion of the undersigned the sample complies / ~~does not comply~~ with the IP/BP/USP/In-House Specifications.

Analysed By		Checked By		Approved By	
Name	G. K. Sharma	Name	J. M. Singh	Name	J. M. Singh
Date	23/11/2023	Date	23/11/2023	Date	23/11/2023

**Manufacturing Plant: Aprazer Healthcare Pvt. Ltd. Village Kotla, PO - Barotiwala, Distt.: Solan, Himachal Pradesh – INDIA**