



Certificate No.
T/398/219

CERTIFICATE OF ANALYSIS

The Drugs and Cosmetics Act 1940 and the rules there under

Name of the Manufacturer	: BDH INDUSTRIES LIMITED.		
Name of the Product	: IMIPRAMINE TABLETS 25 mg		
MFG Lic No.	: 608	Mfg Dt.	: 02/2019
Sample received as	: Final Product	Exp Dt.	: 01/2022
Batch No.	: 180219	Date of Receipt	: 06/03/2019
Quantity manufactured	: 20,60,000 Tablets	Date of Report	: 14/03/2019
Quantity for analysis	: 7 X 10 Tablets (From blister packing)		

RESULTS OF ANALYSIS

TABLETS

TEST		OBSERVATION			LIMIT / SPECIFICATION	
Description		Orange, circular and biconvex sugar coated tablets.			Orange, circular and biconvex sugar coated tablets.	
Average weight of tablet		0.3171 g			0.330 g ±15%	
Uniformity of weight		Passes			± 10% of Avg. weight	
Maximum weight		0.336 g			0.3488 g	
Minimum weight		0.309 g			0.2854 g	
Identification		Imipramine: Positive Chloride : Positive			Imipramine: Positive Chloride : Positive	
Related substances		Iminodibenzyl : Complies Secondary spot : Complies			In the chromatogram obtained with solution (1) any spot corresponding to iminodibenzyl is no more intense than the spot in the chromatogram obtained with the solution (3) (0.3%) and any other secondary spot is not more intense than the spot in the chromatogram obtained with solution (2) (0.3%).	
Uniformity of content		Acceptance value :2.0784			NMT 15	
		% of L. Amt. Released			Limits allowed	
Dissolution	Passes	100.17%	96.49%	97.86%	NLT 75% (Q) within 45 Minutes	
		98.67%	97.04%	98.26%		
Name of the Ingredients assayed		Labelled amt per tablet		Obs. Amt. per tablet	% of L. Amt.	Limits allowed
Imipramine Hydrochloride		25 mg		25.076 mg	100.30%	92.5% to 107.5%

RESULT: From the above tests, I certify that the sample complies with the prescribed standards of quality as per BP and additional dissolution test as per USP.

14/03/2019			
	SAI SWETHA	M.S. ALARKAR	MS. M. V. MHATRE
DATE	ANALYST	APPROVED CHEMIST	QC MANAGER