

ANPHAR
Laboratories Pvt. Ltd.
(A WHO-GMP Certified Company)

CERTIFICATE OF ANALYSIS

PRODUCT NAME	TRIFLUOPERAZINE HYDROCHLORIDE BP	PRODUCT CODE	TH
BATCH NO.	TH- 2402633	BATCH SIZE	90 KG
DATE OF MFG.	FEBRUARY-2024	DATE OF EXP.	JANUARY-2029
DATE OF SAMPLING	21-02-2024	SAMPLE QUANTITY	20gm
DATE OF RELEASE	17-04-2024	ANALYTICAL REPORT NO.	ANP/ FG/088/23-24

TESTS	SPECIFICATIONS	OBSERVATIONS
DESCRIPTION	A White to pale yellow crystalline powder hygroscopic.	White crystalline powder, slightly hygroscopic
SOLUBILITY	Freely soluble in water, soluble in alcohol, practically insoluble in ether.	Complies
MELTING POINT	At about 242°C with decomposition.	242°C
IDENTIFICATION		
A. ULTRAVIOLET ABSORPTION	Shows the absorption maximum at 255nm. The specific absorbance at 255 is about 650.	Complies
B. TEST FOR PHENOTHIAZINES	Complies with Identification test for phenothiazines, by thin-layer chromatography.	Complies
C. TEST WITH MALEIC ACID	The residue melts at 192°C	Complies
D. TEST WITH SULPHURIC ACID	Red colour develops	Complies
E. REACTION OF CHLORIDES	Shows Reaction a' characteristic of chlorides	Complies
PH	Between 1.6 to 2.5 determined on 10 % w/v solution.	1.83
RELATED SUBSTANCES	Should Comply	Complies.
TOTAL NUMBER OF IMPURITIES	NMT 0.5%	Complies
LOSS ON DRYING	NMT 1.5 %.	0.44%
SULPHATED ASH	NMT 0.1%	0.05%
ASSAY(ON DRIED BASIS)	99.0% to 101.0%	99.80%
RESIDUAL SOLVENTS	Toluene NMT 880ppm n-Hexane NMT 290ppm	23.67ppm 1.67ppm
MICROBIOLOGICAL LIMITS		
1) TOTAL AEROBIC COUNTS	≤ 1000cfu/g	LT 100cfu/g
2) TOTAL COMBINED MOULDS AND YEASTS	≤ 100cfu/g	LT 10cfu/g
3) ESCHERICHIA COLI	Absent/g	Absent

IN THE OPINION OF UNDERSIGNED, THE SAMPLE REFERED TO ABOVE IS OF STANDARD QUALITY AND COMPLIES AS PER BP

Prepared By(Sign. Date)	Checked and Reviewed By(Sign and Date)	Approved By(Sign and Date)
Supervisor and Above Quality Control	Head - Quality Control	Head- Quality Assurance
<i>[Signature]</i> 17-04-2024	<i>[Signature]</i> 17-04-2024	<i>[Signature]</i> 17-04-2024

SOP NO: ANP/QCD/013/00

Revision No. :00

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