

Date: 01/06/2022


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CERTIFICATE OF ANALYSIS


PRODUCT : BUTORPHANOL TARTRATE **DATE OF MFG.** : MAY - 2022
BATCH No. : F11800322/007 **RETEST DATE** : APR - 2026
A.R. NO. : FP220990 **DATE OF ANALYSIS** : 23/05/2022
QUANTITY : 1 x 0.50 Kg

TESTS	RESULTS	SPECIFICATIONS
Description	White powder	White powder
Identification		
FT-IR	Complies	Corresponds to standard
TLC	Complies	The R _f value of the principal spot in the chromatogram of the test preparation corresponds to that in the chromatogram of the standard preparation, as obtained for test A in the chromatographic purity test.
Solubility	Complies	Soluble in dilute acids, sparingly soluble in water, slightly soluble in methanol. Insoluble in alcohol, ethyl acetate, chloroform, ethyl ether and hexane. Its solutions are slightly acidic.
Water content (% w/w)	0.07%	Not more than 2.0%
Specific rotation	-62.5°	Between -60° and -66°
Residue on ignition (% w/w)	0.04%	Not more than 0.1%
Heavy metals	Less than 0.003%	Not more than 0.003%
Melting point range	217.9°C – 218.8°C	In between 217°C to 219°C with decomposition.
Assay (On Anhydrous Basis) (%w/w)	99.2%	98.0% and 102.0%
The material complies with current USP specification		

COA Re-issued with corrected result for Specific rotation.

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TESTS	RESULTS	SPECIFICATIONS
# Purity and impurity content by HPLC (area %)		
Purity	99.95%	Not less than 99.50%
Impurity-A	BDL*	Not more than 0.15%
Any other impurity	BDL*	Not more than 0.10%
Total impurities	BDL*	Not more than 0.50%
# Residual solvents by GC (w/w) Method-I		
Methanol	BLQ**	Not more than 3000 ppm
Acetone	BLQ**	Not more than 5000 ppm
Isopropyl alcohol	BLD***	Not more than 5000 ppm
Dichloromethane	Not detected	Not more than 600 ppm
t-Butanol	Not detected	Not more than 1000 ppm
Tetrahydrofuran	Not detected	Not more than 720 ppm
Toluene	Not detected	Not more than 890 ppm
# Residual solvents by GC (w/w) Method-II		
DMF	Not detected	Not more than 880 ppm
Xylene	Not detected	Not more than 2170 ppm
The material complies with # In-house specification		

BDL*- Below disregard Limit, BLQ**- Below Limit of Quantification,
BLD***- Below Limit of detection

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