



DIVI'S LABORATORIES LIMITED QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

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Product: DEXTROMETHORPHAN HBr

Grade	BP/USP	Mfg. Date	Nov-2025
Batch Number	S-A-0210126	Retest Date	Oct-2030
Batch Quantity	500.90 Kg	Expiry Date	NA
Dispatch Quantity	500 Kg	Rev. No.	SG/01/13
Q.A.R. No.	DU1/FP/2601/000482	Sl. No.	DU1FP26000203/2

S. No.	TEST	SPECIFICATION	RESULT
1	STANDARD (PHARMACOPOEIAL)		
1.1	Description	Almost white crystalline powder	White crystalline powder
1.2	Solubility		
1.2.1	In Alcohol	Freely soluble in Alcohol.	Freely soluble
1.2.2	In Chloroform	Freely soluble in Chloroform.	Freely soluble
1.2.3	In Water	Sparingly soluble in Water.	Sparingly soluble
1.2.4	In Ether	Insoluble in Ether.	Insoluble
1.3	Appearance of solution	A 5.0% w/v solution in alcohol will be clear and colourless.	Solution is clear and colorless
1.4	Melting Point	About 125°C (with decomposition)	124.7°C to 126.2°C
1.5	Identification by Spectroscopic Identification Tests - Infrared Spectroscopy (USP)	Sample spectrum should match with standard spectrum	Concordant with working standard spectrum
1.6	Identification by IR Spectrum (BP)	Concordant with WS.	Concordant with working standard spectrum
1.7	Identification by Specific optical rotation	+28° to +30° (Anhydrous substance)	28.82 °
1.8	Identification Test for Levomethorphan content by HPLC (USP)	Not more than 0.10%	Not detected
1.9	Identification Test for Bromide	Acidify 2mL of solution with dilute nitric acid and add 0.4mL of silver nitrate solution. Pale yellow precipitate is formed.	Pale yellow precipitate is formed
1.10	Identification by Enantiomeric purity by HPLC (BP)	Should comply with the Enantiomeric purity by HPLC test	Complies
1.11	Enantiomeric purity by HPLC		

Remarks: APPROVED (Sample Conforms to above Specification)

Special Comments: --

Analyst	M.Srilatha	Person In-charge of testing	M.Suresh
Date	Feb 20 2026 4:08PM	Date	Feb 20 2026 4:21PM
Printed by: JILANI.MULLA	Printed On: Feb 26 2026 8:18AM	Copy No.: 2	Page No.: 1 of 3

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DU1FP26000203/2

“An ISO-9001, ISO-14001 and ISO-45001 Triple certified company”

FACTORY : UNIT-1, Lingojigudem Village, Choutuppal Mandal, Yadadri Bhuvanagiri District, Telangana - 508 252, INDIA.
Tel. : +91-8694 257001, Fax : +91-8694 257006, CIN : L24110TG1990PEC011854

CORPORATE OFFICE : DIVI Towers, 1-72/23(P)/DIVIS/303, Cyber Hills, Gachibowli, Hyderabad - 500 032, Telangana, India.



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S. No.	TEST	SPECIFICATION	RESULT
1.11.1	Impurity E	Not more than 0.10%	Not detected
1.12	pH	A 1 in 100 solution in water has a pH between 5.2 and 6.5	5.46
1.13	Water (USP)	Between 3.5% and 5.5%w/w	4.98 %w/w
1.14	Water (BP/EP)	Between 4.0% and 5.5%w/w	5.05 %w/w
1.15	Residue on ignition	Not more than 0.1%w/w	0.03 %w/w
1.16	N,N Dimethyl aniline	Colour is not more than that of standard (0.001%w/v)	Less than 0.001%w/v
1.17	Acidity or Alkalinity	NMT 0.4ml of 0.01M HCl is consumed	0.3 mL
1.18	Phenolic compounds	No blue-green colour develops.	No Blue-green color observed
1.19	Related substances by HPLC		
1.19.1	Unspecified impurities (For Each impurity)	Not more than 0.10%	<0.05%
1.19.2	Total impurities	Not more than 0.5%	<0.05%
1.20	Assay by Titration	NLT 99.0%w/w and NMT 101.0%w/w calculated on anhydrous basis	99.58 %w/w
1.21	Assay by HPLC	NLT 98.0%w/w and not more than 102.0%w/w calculated on anhydrous basis.	99.81 %w/w
2	ADDITIONAL TESTS (IN-HOUSE)		
2.1	Residual solvents		
2.1.1	Methanol	Not more than 200 ppm	BDL (<10ppm)
2.1.2	Acetone	Not more than 200 ppm	BDL (<10ppm)
2.1.3	Toluene	Not more than 250 ppm	BDL (<10ppm)
2.2	Related substances by HPLC		
2.2.1	Any known individual impurity (A or B or C or D)	Not more than 0.5%	<0.05%
2.2.2	Any other known	Not more than 0.25%	<0.05%

Remarks: APPROVED (Sample Conforms to above Specification)

Special Comments: --

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S. No.	TEST	SPECIFICATION	RESULT
	individual impurity (A or B or C or D)		
2.2.3	Any other unknown impurity	Not more than 0.10%	<0.05%
2.2.4	Total impurities	Not more than 1.0%	<0.05%

Remarks: APPROVED (Sample Conforms to above Specification)

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