



DIVI'S LABORATORIES LIMITED
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product: DILTIAZEM HCL			
Grade	Ph.Eur	Mfg. Date	Jul-2018
Batch Number	AZ-0560718	Retest Date	Jun-2023
Batch Quantity	338.00 Kg	Expiry Date	NA
Dispatch Quantity	200 Kg	Rev. No.	AZ/01/07-A0
Q.A.R. No.	DU1/FP/1807/002228	Sl. No.	DU1FP18001692/2

S. No.	TEST	SPECIFICATION	RESULT
1	STANDARD (PHARMACOPOEIAL)		
1.1	Appearance	A White or almost white crystalline powder.	White crystalline powder
1.2	Solubility		
1.2.1	In methanol	Freely soluble in methanol.	Freely soluble
1.2.2	In water	Freely soluble in water.	Freely soluble
1.2.3	In methylene chloride	Freely soluble in methylene chloride.	Freely soluble
1.2.4	In anhydrous ethanol	Slightly soluble in anhydrous ethanol.	Sparingly soluble
1.3	Melting point	About 213°C (with decomposition)	210.9°C to 212.3°C
1.4	Identification by IR spectrum	IR spectrum is concordant with that of working standard.	Concordant with working standard
1.5	Identification by Chlorides	Positive.	Positive
1.6	Appearance of solution	5.0% Aq. solution should be clear & colourless	Clear and colourless
1.7	pH (1% in water)	Between 4.3 and 5.3	4.8
1.8	Specific optical rotation (at 20°C)	Between +115° and +120°	119°
1.9	Related substances by HPLC		
1.9.1	Desacetyl Diltiazem Hydrochloride	Not more than 0.3%w/w	0.0 %w/w
1.9.2	Unspecified impurities	Not more than 0.10%w/w	0.03 %w/w
1.9.3	Total impurities	Not more than 0.3%w/w	<0.05%w/w
1.10	Loss on drying (105°C for 2 hrs)	Not more than 0.5% w/w	0.2 %w/w
1.11	Sulphated ash	Not more than 0.1% w/w	0.0 %w/w
1.12	Assay by titration (on dried basis)	NLT 98.5% w/w and NMT 101.0% w/w	99.5 %w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Special Comments: "The above material fully conforms to the Pharm.Eur. Specification and the additional requirements of the European Certificate of Suitability R1 – CEP 1999 – 156-Rev 08".

P.O.NO.BI180994

Analyst	M.Sriatha	Person In-charge of testing	K Sekhar Babu
Date	Jul 26 2018 1:50PM	Date	Jul 26 2018 3:32PM
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"An ISO-9001, ISO-14001 and OHSAS-18001 Triple certified company"

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S. No.	TEST	SPECIFICATION	RESULT
2	ADDITIONAL TESTS		
2.1	Dimethyl Amino Pyridine (DMAP) content by GC (%w/w)	Not more than 0.05%w/w	Not detected
2.2	Residual solvents		
2.2.1	Methanol	Not more than 1000 ppm	591 ppm
2.2.2	Isopropyl alcohol	Not more than 1000 ppm	233 ppm
2.2.3	Toluene	Not more than 500 ppm	6 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

Special Comments: "The above material fully conforms to the Pharm.Eur. Specification and the additional requirements of the European Certificate of Suitability R1 – CEP 1999 – 156-Rev 08".

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