

Quality Control Laboratory Certificate of Analysis

RAW MATERIAL

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Name Of Material : CARVEDILOL EP Manufactured By : SYMED LABS LIMITED UNIT-II Supplied By : SYMED LABS LTD. Batch No. : 2CAN0010120 Advice Sheet No : 010003486461 Quantity : 100.000 KG Sample Quantity : 0.04 KG Analysis as per : RMT/320 CEP No. : Not Applicable	Material No. : 1000364 Inspection Lot No. : 010003486461 Specification No. : 10012201 Version No. : 5 Date Of Receipt. : 17.01.2020 Manufacturing Date : JAN-2020 Expiry Date : DEC-2024 Analytical Report No.: ARD11G0056 Date Of Report : 31.01.2020
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Test	Limit	Results
Appearance	White or almost white, crystalline powder.	White, crystalline powder.
Solubility	Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in ethanol (96 per cent). It is practically insoluble in dilute acids.	Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in ethanol (96 per cent). It is practically insoluble in dilute acids.
Identification: (A) By IR	The IR spectrum of the test sample should concordant with IR spectrum of reference/working standard.	The IR spectrum of the test sample is concordant with IR spectrum of working standard.
Identification: (B) By P-XRD*	The XRD Diffractogram pattern of Carvedilol sample should have characteristic peaks of Carvedilol form-II comprising 2θ angle values at 5.9°, 14.9°, 17.6°, 18.5° and 24.4° ± 0.2° measured in X-ray Diffractometer.	The XRD Diffractogram pattern of Carvedilol sample have characteristic peaks of Carvedilol form-II comprising 2θ angle values at 5.8035°, 14.7975°, 17.4941°, 18.4316° and 24.3304° measured in X-ray Diffractometer.

Reviewed By	Approved By
Name: Anamika Salaria	Name: Siddhesh Doshi
Date: 31.01.2020	Date: 31.01.2020
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TORRENT PHARMACEUTICALS LTD.

INDRAD-382 721, TAL : KADI,
City: INDRAD, Dist.: MEHSANA, INDIA

Torrent House
Off Ashram Road
Ahmedabad-380 009
India.
Phone: (079) 2659 9000
Fax: (079) 2658 2100

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Name Of Material : CARVEDILOL EP	Material No. : 1000364
Manufactured By : SYMED LABS LIMITED UNIT-II	Inspection Lot No. : 010003486461
Supplied By : SYMED LABS LTD.	Specification No. : 10012201
Batch No. : 2CAN0010120	Version No. : 5
Advice Sheet No : 010003486461	Date Of Receipt. : 17.01.2020
Quantity : 100.000 KG	Manufacturing Date : JAN-2020
Sample Quantity : 0.04 KG	Expiry Date : DEC-2024
Analysis as per : RMT/320	Analytical Report No.: ARD11G0056
CEP No. : Not Applicable	Date Of Report : 31.01.2020

Test	Limit	Results
Related substances (By HPLC)#:(A) Impurity A	Not more than 0.20 %	Below disregard limit
Related substances (By HPLC):(B) Impurity D	Not more than 0.15 %	Below disregard limit
Related substances (By HPLC):(C) Impurity C	Not more than 0.02 %	Not Detected
Related substances (By HPLC):(D) Unspecified impurities	Not more than 0.10 %	Below disregard limit
Related substances (By HPLC)#:(E) Sum of impurities other than C	Not more than 0.50 %	Below disregard limit
Heavy Metals	Not more than 10 ppm.	Less than 10 ppm
Loss on drying#	Not more than 0.50 % w/w	0.14 % W/W
Sulfated Ash	Not more than 0.1 % w/w	0.03 % W/W
Assay	Not less than 99.0 % and not more than 101.0 % (on dried basis).	100.2 %
Residual solvents (By GC): (A) Methanol *	Not more than 1000 ppm	4 ppm

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Quantity : 100.000 KG	Manufacturing Date : JAN-2020
Sample Quantity : 0.04 KG	Expiry Date : DEC-2024
Analysis as per : RMT/320	Analytical Report No.: ARD11G0056
CEP No. : Not Applicable	Date Of Report : 31.01.2020

Test	Limit	Results
Residual solvents (By GC): (B) Ethyl acetate *	Not more than 3000 ppm	479 ppm
Particle size (By Malvern): (A) Below 50 μ *	Not less than 70 %	93 %
Particle size (By Malvern): (B) Below 100 μ *	Not less than 95 %	100 %

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Remarks:Complies as per 10012201 Specification.

Sampling Plan : Z001

* Additional In-house tests.# Stringent limit than Ph.Eur.

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