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The Government Pharmaceutical Organization
Rangsit Pharmaceutical Production Plant

DOCUMENT NUMBER:	RPP-SP-QC-RM-119
DOCUMENT TITLE:	SPECIFICATION OF CARVEDILOL (ITEM NO. 44110045)
DOCUMENT NOTES:	

Document Information

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Control Information

Author:	PORNTHIP_W	Previous Number:	
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THE GOVERNMENT PHARMACEUTICAL ORGANIZATION RANGSIT PHARMACEUTICAL PRODUCTION PLANT		
TITLE	**SPECIFICATION OF CARVEDILOL (ITEM NO. 44110045)**	**Rev. 01**
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REVISION HISTORY

Rev.No.	Change & Reason For Change	Effective Date
01	Initial Release	As per effective date in electronic system

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A. Specification

No.	Test parameters	Specifications
01	Description	White or nearly white, crystalline powder.
02	Solubility	Slightly soluble in alcohol; practically insoluble in water, and in dilute acids.
03	Identification (A)	The infrared absorption spectrum of the sample exhibits maxima only at the same wavelengths as that of a similar preparation of the corresponding standard.
	Identification (B)	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
	Identification (XRPD)(*)	The X-Ray diffractogram of the sample should match with the Carvedilol (Form II).
04	Assay	98.0-102.0% w/w of $C_{24}H_{26}N_2O_4$ calculated on the dried basis.
05	Residue on ignition	Not more than 0.1%
06	Heavy metals(*)	Not more than 10 ppm
07	Organic impurities a. Carvedilol related compound E b. Carvedilol related compound A c. Carvedilol Bisalkylpyrocatechol derivative (if present) d. Carvedilol related compound C e. Carvedilol related compound D f. Carvedilol related compound B g. Any other individual impurity h. Total impurities	 Not more than 0.1%. Not more than 0.1%. Not more than 0.15 %. Not more than 0.02%. Not more than 0.1%. Not more than 0.1%. Not more than 0.10%. Not more than 0.5%.
08	Loss on drying	Not more than 0.5% w/w.
09	Residual solvents(*) a. Methanol b. Ethanol c. Acetone d. Dichloromethane e. Ethyl acetate f. Monoglyme g. Isopropyl acetate	 Not more than 1000 ppm Not more than 1000 ppm Not more than 1000 ppm Not more than 500 ppm Not more than 4000 ppm Not more than 100 ppm Not more than 1000 ppm
10	Particle size(*) • d (0.5) • d (0.9)	 Not more than 10 µm Not more than 25 µm

* *In-house specification.*

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B. Storage condition

Preserve in tight containers, and store at controlled room temperature.

C. References

1. USP39, Carvedilol monograph, page 2958-2960.
2. Raw Material Specification Document No. RMS-RA-79N54170-01, Carvedilol.

D. Product Information

Approved source (s)	Refer to current version of Approved Supplier List (ASL) and/or Provisional Supplier List (as follow RPP-SOP-QA-029: Supplier Qualification) of Carvedilol (Item No. 44110045).
Sampling plan	Identification : Every container. Other tests : $\sqrt{N} + 1$.
Testing procedure	Test to be performed as per current version of Standard Testing Procedure of Carvedilol (Item No. 44110045).
Retest period	1 year.

Signature Manifest

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All dates and times are in GMT +7.

Pls. review RPP-SP-QC-RM-119 SPECIFICATION OF CARVEDILOL (ITEM NO. 44110045)

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