



Certificate of Analysis

Product	: Carvedilol Phosphate hemihydrate		
Sr.No.	Tests	Observations	Specifications
01.	Description	Off-white crystalline powder	White to off-white crystalline powder
02.	Solubility	Complies	Soluble in DMSO
03.	Moisture Content	1.90%	1.6 – 2.0%
04.	Identification by : Infrared Absorption	Complies	The IR spectrum should be concordant with the spectra obtained with Carvedilol phosphate working standard.
	Phosphate	Complies	Should be Positive.
	HPLC	Complies	In the test for assay the reaction time and size of the principle peak in the test solution should be similar with that of standard.
05.	Residue on ignition	0.05%	Not more than 0.1%
06.	Heavy Metals	Less than 20 ppm	Not more than 20 ppm
07.	Related substance by HPLC		
	*** Impurity C	Not detected	Not more than 0.02%
	Single Impurity	0.03%	Not more than 0.10%
	Total Impurities	0.12%	Not more than 0.5%
08.	Assay on dry basis (by HPLC)	101.2%	98.0 to 102.0%
09	Residual solvents Acetonitrile	35 ppm	Not more than 400 ppm