LoGiCal®
produced by LGC

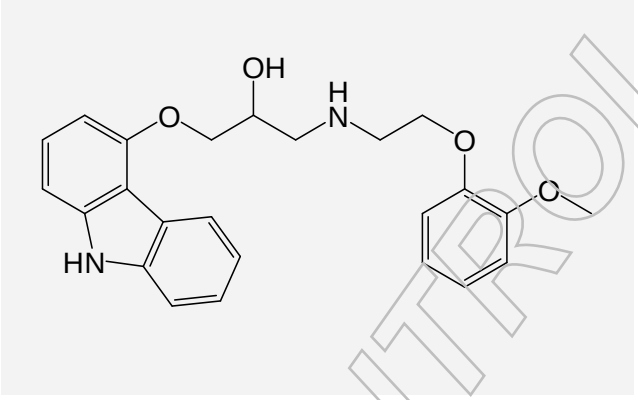
Certificate of Analysis

Reference Substance

Carvedilol

Catalogue Number:	LGCFOR0291.00
Lot Number:	11932
Molecular Formula:	$C_{24}H_{26}N_2O_4$
Molecular Weight:	406.47
CAS Number:	[72956-09-3]

Long-term Storage:	2 to 8 °C, dark
Appearance:	white solid
Melting Point:	117 °C
Assay 'as is':	99.8 %



Date of shipment: **2016-May-20**

This certificate is valid for two years from the date of shipment provided the substance is stored under the recommended conditions.

Release Date: 2012-01-23

LGC GmbH

Dr. Sabine Schröder
Product Release

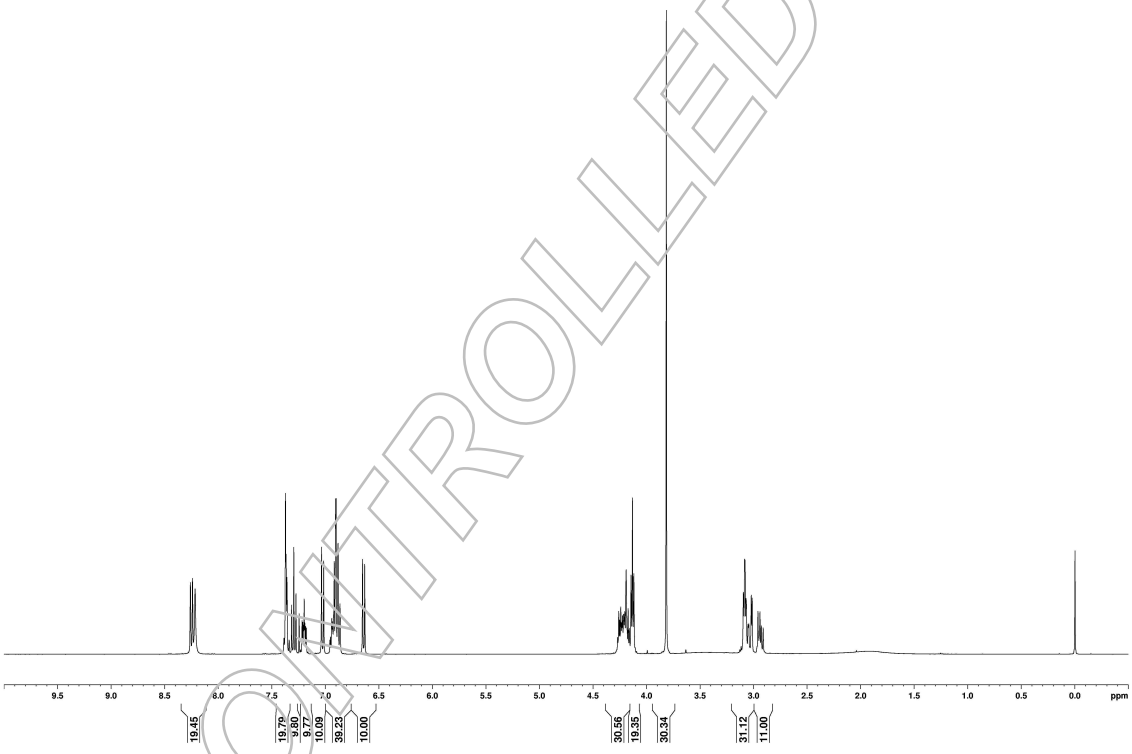
I. Identity

The identity of the reference substance was established by following analyses.

Ia. ^{1}H-NMR Spectrum

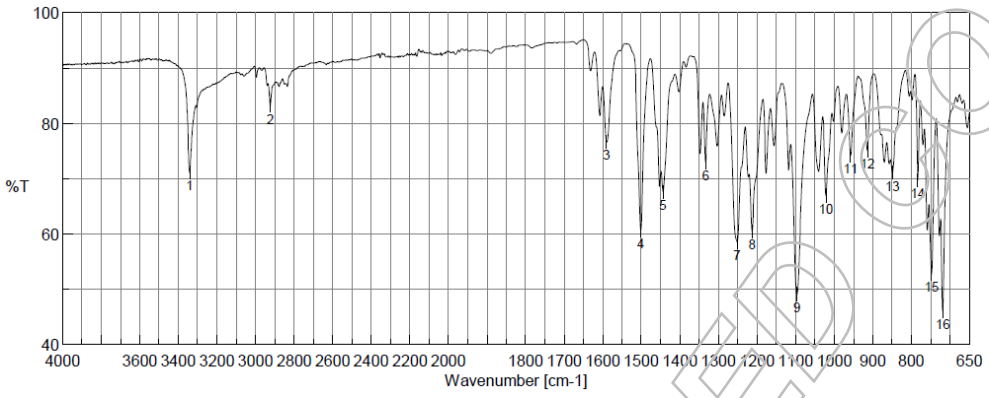
Conditions: 400 MHz, $CDCl_3$

The structure is confirmed with the signals of the spectrum and their interpretation.



Ib. IR Spectrum

Method: Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy



Result of Peak Picking

No.	Position	Intensity
1	3341.07	71.1168
2	2923.56	83.1992
3	1590.02	76.6033
4	1501.31	60.6047
5	1443.46	67.6123
6	1333.53	72.916
7	1251.58	58.5712
8	1213.01	60.404
9	1096.33	49.1283
10	1021.12	66.9362
11	957.484	74.1716
12	914.093	75.0816
13	849.49	71.0415
14	782.958	69.6638
15	747.281	52.8337
16	718.354	46.0063

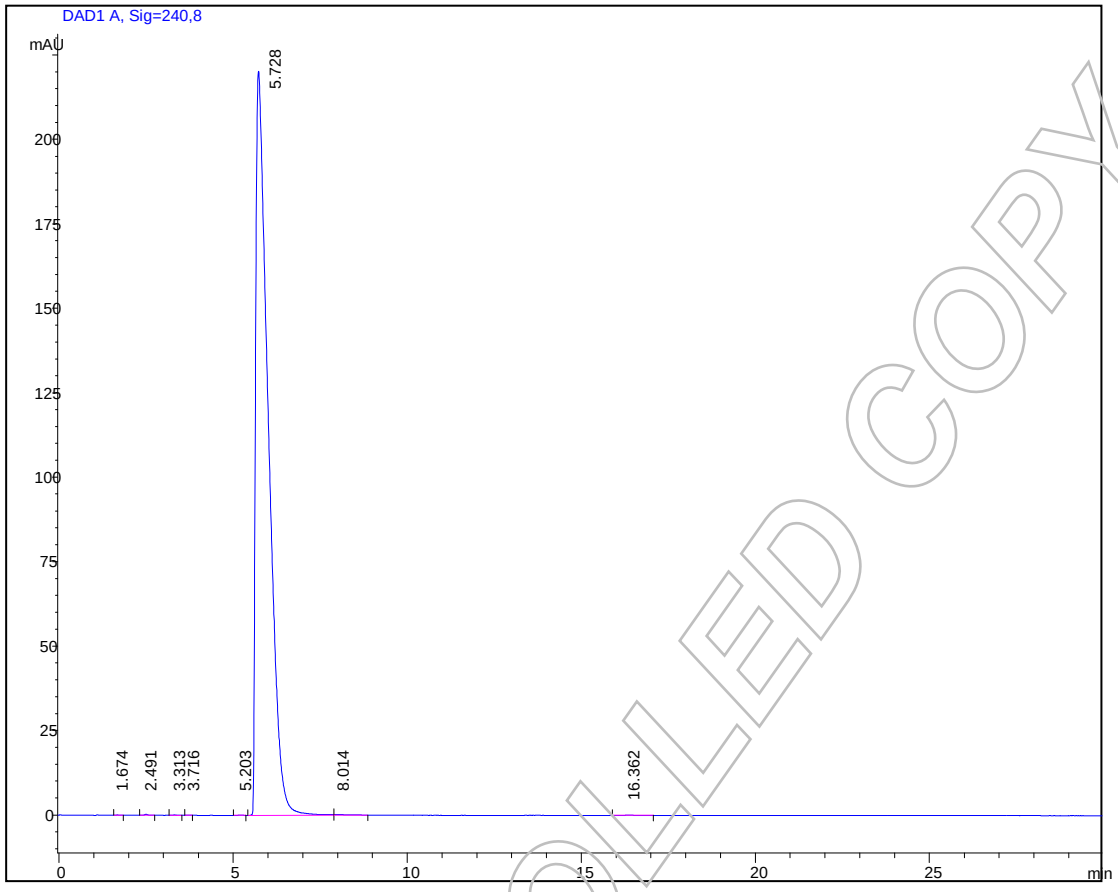
The signals of the IR spectrum and their interpretation are consistent with the structural formula.

II. Purity

The purity of the reference substance was analysed by high performance liquid chromatography (HPLC).

HPLC Conditions:

Column:	**Conditions:**	**Detector:**	**Injector:**
RP 60 Select B	1.0 ml/min, 40 °C	DAD	Auto
5 µm, 125 x 4 mm	Water/Acetonitrile 65/35 (v/v);	240 nm	4 µl; 0.4412 mg/ml in
	0.1 % H_3PO_4		Water/Acetonitrile 50/50 (v/v)



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	1.67	0.53	0.01
2	2.49	1.95	0.04
3	3.31	0.74	0.01
4	3.72	0.36	0.01
5	5.20	0.43	0.01
6	5.73	5559.53	99.80
7	8.01	4.84	0.09
8	16.36	2.28	0.04
Totals		5570.66	100.00

For the calculation the system peaks were ignored. The content of the analyte was determined as ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100 %.

Results:

Average	99.79 %
Number of results	n=6
Standard deviation	0.02 %

III. Water Content

Method: Karl Fischer titration

No significant amounts of water were detected (< 0.05 %).

IV. Residual Solvents

Method: ^{1}H-NMR

No significant amounts of residual solvents were detected (< 0.05 %).

V. Final Result

Total impurities (HPLC)	0.21 %
Water content	n. d. (not detected)
Residual solvents	n. d. (not detected)
Assay (100 % method) [1]	99.79 %

The assay is assessed to be 99.8 % ‘as is’

The assay 'as is' is equivalent to the assay based on the not anhydrous and not dried substance respectively.

[1] The calculation of the 100 % method follows the formula:

$$\text{Assay (\%)} = (100\ \% - \text{KF} - \text{RES}) * \frac{\text{Purity HPLC (\%)}}{100\ \%}$$

Water (KF) and Residual solvents (RES) are considered as absolute contributions, HPLC purity is considered as relative contribution.