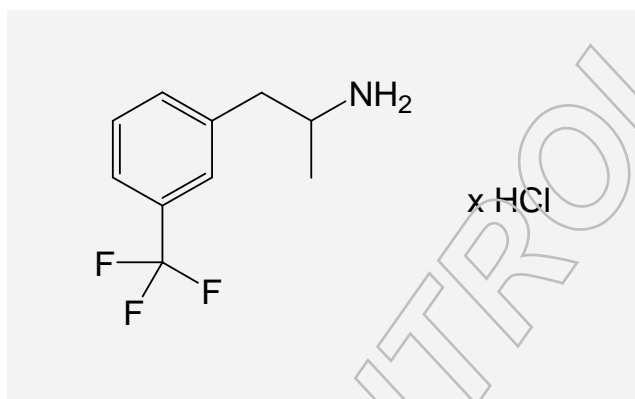


Certificate of Analysis

Reference Substance

Norfenfluramine Hydrochloride

Catalogue Number:	LGCFOR0608.01	Long-term Storage:	2 to 8 °C, dark
Lot Number:	2409	Appearance:	white solid
Molecular Formula:	C ₁₀ H ₁₂ F ₃ N HCl	Melting Point:	164 °C
Molecular Weight:	239.67	Assay 'as is':	97.6 %
CAS Number:	[673-18-7]		



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: 2010-06-02

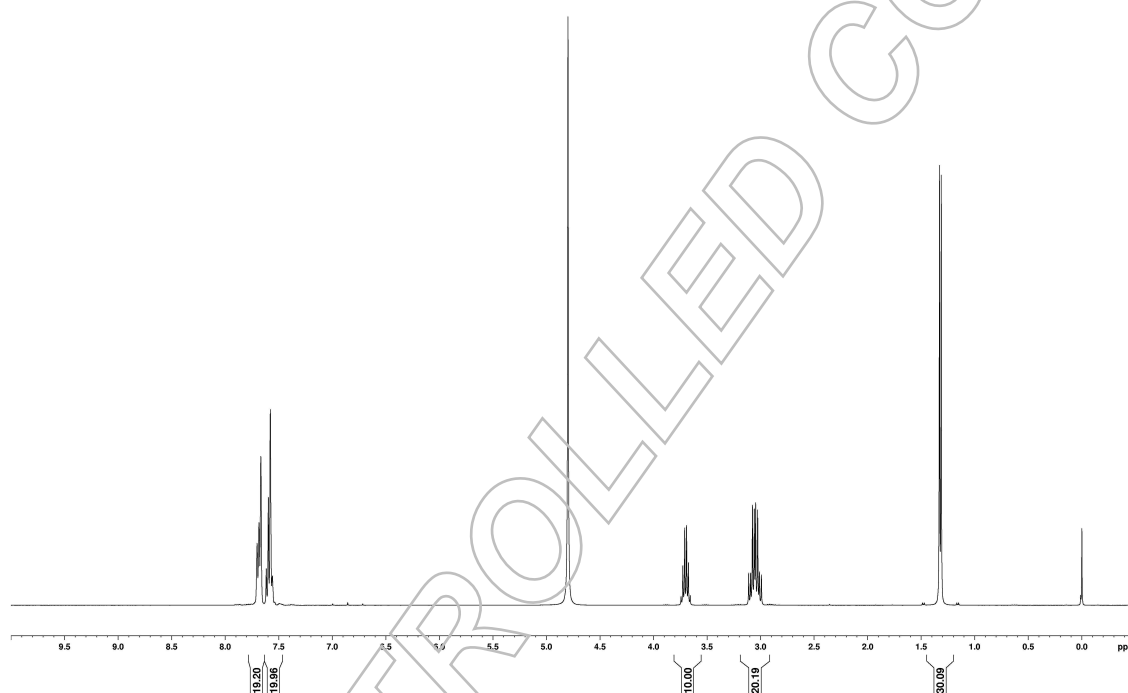
LGC GmbH

Dr. Sabine Schröder
Product Release

I. Identity

The identity of the reference substance was established by $^1\text{H-NMR}$ spectroscopy. The structure is confirmed with the signals of the spectrum and their interpretation.

Conditions: 400 MHz, D_2O



II. Purity

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

HPLC Conditions:

Column:

Pro C 18 RS
5 μm , 150 x 4.6 mm

Conditions:

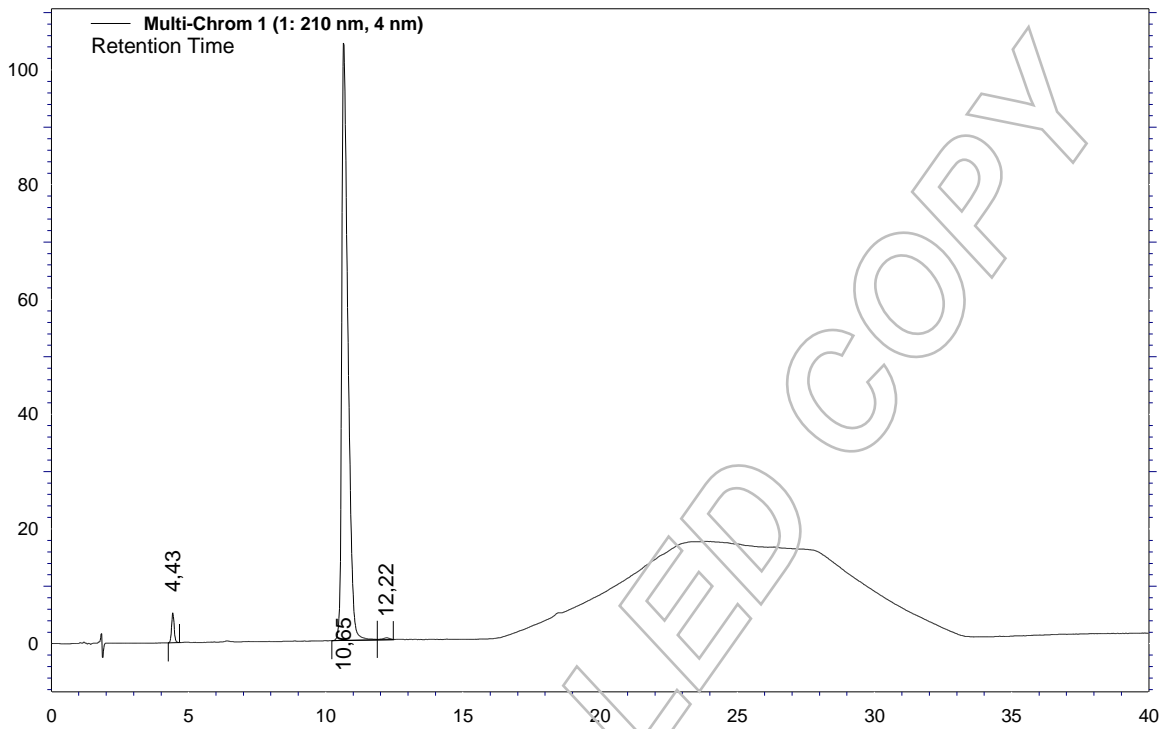
1.0 ml/min, 40 °C
0 – 13 min Water/Acetonitrile 85/15
13 – 20 min Water/Acetonitrile to 70/30
20 – 25 min Water/Acetonitrile 70/30
25 – 30 min Water/Acetonitrile to 85/15
30 – 40 min Water/Acetonitrile 85/15 (v/v);
0.1 % H_3PO_4

Detector:

DAD
210 nm

Injector:

Auto
6 μl ; 0.05108 mg/ml in
Water



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	4.43	33338	2.00
2	10.65	1626974	97.65
3	12.22	5881	0.35
Totals		1666193	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 97.65 %
Number of results n=6
Standard deviation 0.04 %

III. Water Content

Method: Karl Fischer titration

Results:

Average	0.06 %
Number of results	n=3
Standard deviation	0.01 %

IV. Residual Solvents

Method: ¹H-NMR

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

V. Final Result

Total impurities (HPLC)	2.35 %
Water content	0.06 %
Residual solvents	n. d. (not detected)
Assay (100 % method) ¹	97.59 %

The assay is assessed to be 97.6 % '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.

LGCFOR0608.01 Lot Number 2409

LGC GmbH, Im Biotechnologiepark, TGZ II, D-14943 Luckenwalde, Germany