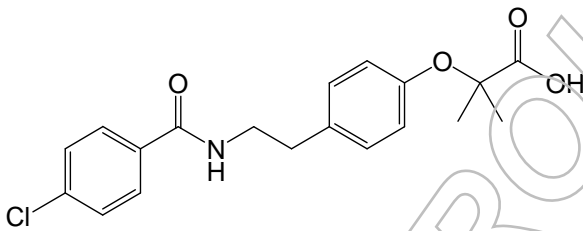




Certificate of Analysis

Reference Standard

Bezafibrate



Molecular Formula: $C_{19}H_{20}ClNO_4$
Molecular Weight: 361.82
CAS Number: [41859-67-0]

Catalogue Number: MM0063.00
Lot Number: 63.00.08.03
Long-term Storage: 2 to 8 °C, dark
Appearance: white solid
Melting Point: 182 °C
Assay 'as is': 99.8 %

Date of shipment: **2017-September-05**

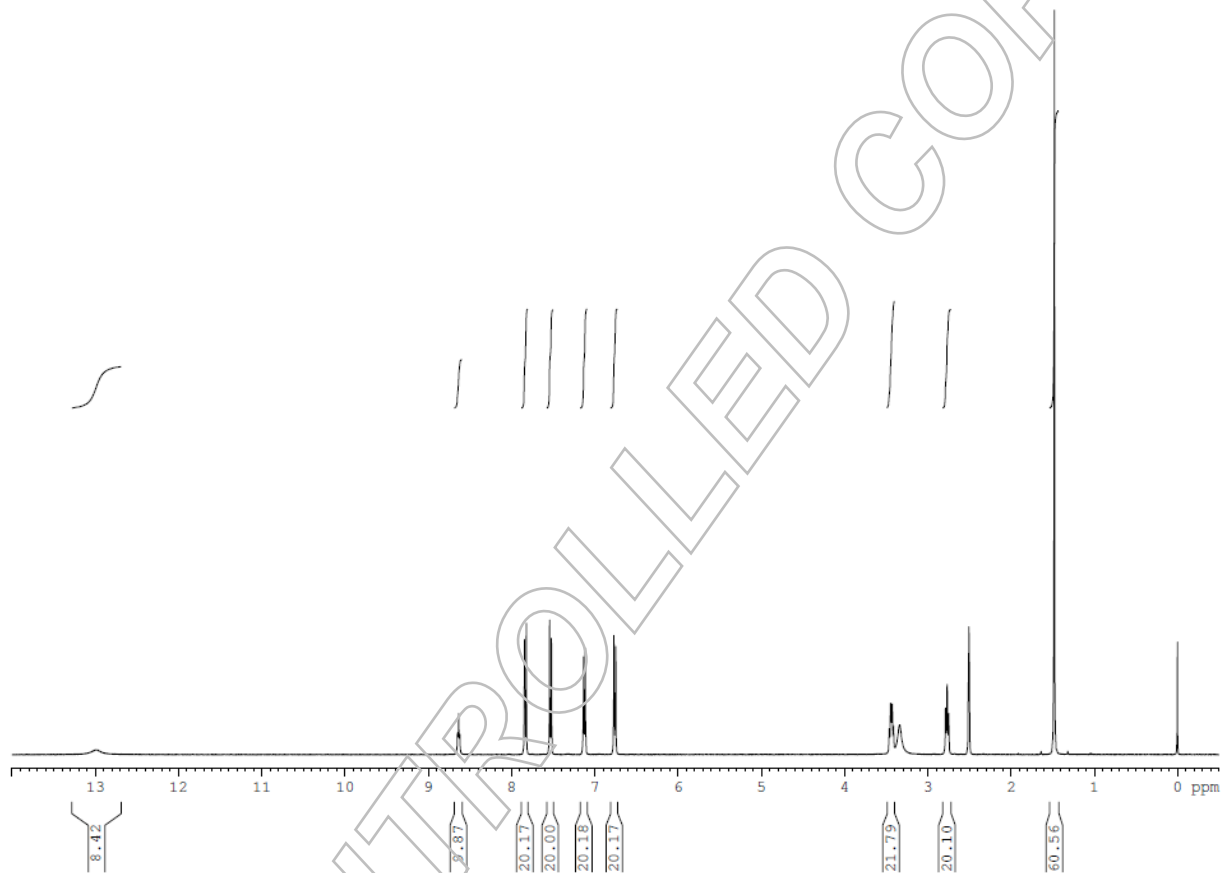
This certificate is valid for two years from the date of shipment provided the substance is stored under the recommended conditions.



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, DMSO-d_6



II. Purity

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

HPLC Conditions:

Column:

Hypersil Gold (C18)
5 μm , 150 x 4.6 mm

Conditions:

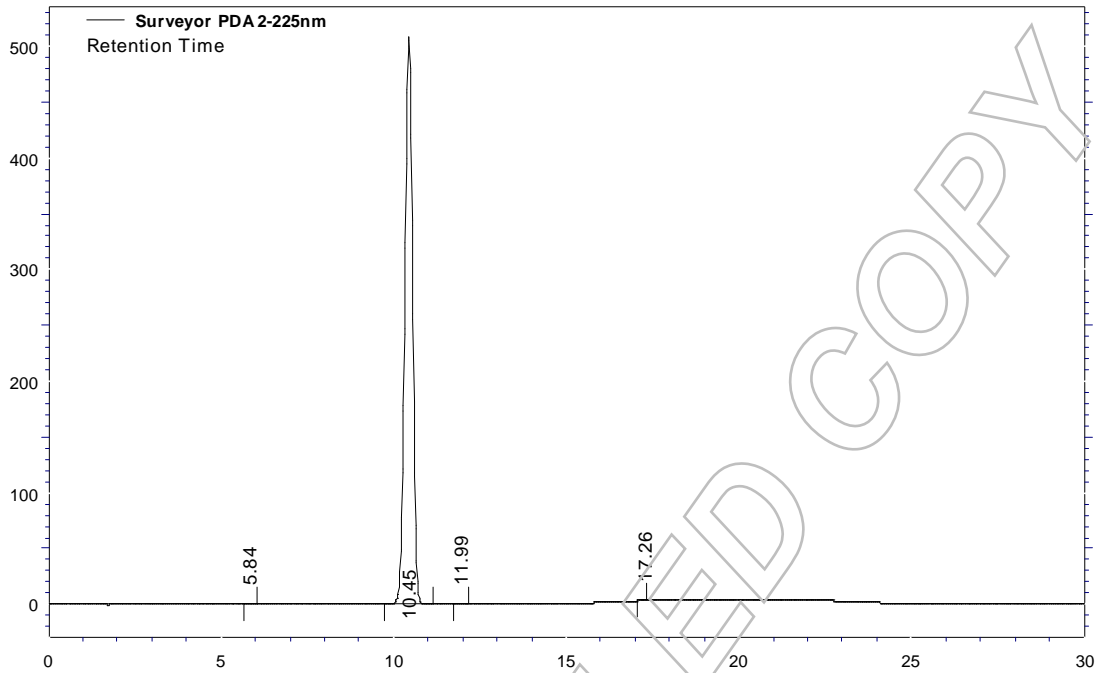
1.0 ml/min, 40 $^\circ\text{C}$
0-12 min Water/Acetonitrile 65/35
12-15 min Water/Acetonitrile to 55/45
15-19 min Water/Acetonitrile 55/45
19-22 min Water/Acetonitrile to 65/35
22-30 min Water/Acetonitrile 65/35 (v/v);
0.1 % H_3PO_4

Detector:

DAD
225 nm

Injector:

Auto
5 μl ; 0.1334 mg/ml in
Acetonitrile



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	5.84	4378	0.06
2	10.45	7762997	99.91
3	11.99	924	0.01
4	17.26	1679	0.02
Totals		7769978	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 99.91 %
Number of results n=6
Standard deviation < 0.01 %



III. Water Content

Method: Karl Fischer titration

Results:

Average	0.07 %
Number of results	n=2

IV. Residual Solvents

Method: $^1\text{H-NMR}$

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

V. Assay by Elementary Analysis (Carbon Titration)

Method: percentage carbon found in relation to percentage carbon as calculated for molecular formula

Results:

Arithmetic mean (n=3)	100.12 % (mass fraction)
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VI. Final Result

Total impurities (HPLC)	0.09 %
Water content	0.07 %
Residual solvents	n. d. (not detected)
Assay (100 % method)	99.84 %

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.

Release Date: 2008-08-28

LGC GmbH

Dr. Sabine Schröder
Product Release