

**CERTIFICATE OF ANALYSIS**

Sigma-Aldrich Laborchemikalien GmbH D-30918 Seelze  
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Seelze, 02.08.2012/415347/12/15713

Order-No.:

Customer-No.:

Order-Code:

Quantity:

Production Date: 18.Jul.2012

Expiry Date: 18.Jul.2017

Article/Product: 34014

Batch : SZBC200XV

Loperamide hydrochloride VETRANAL

**Reference Material (RM)****1. General Information**

Formula: C<sub>29</sub>H<sub>33</sub>ClN<sub>2</sub>O<sub>2</sub> . HCl

CAS-No.: [34552-83-5]

Usage :

Molar mass: 513.50 g/Mole

Recomm. storage temp.: roomtemp.

The estimated uncertainty of a single measurement of the assay can be expected to be 0.5 % relative (confidence level = 95%, n= 6) whereby the assay measurements are calculated by 100% minus found impurities.

**2. Batch Analysis**

Identity (NMR)

Assay (HPLC)

Melting range

Water (Karl Fischer)

Date of Analysis

complying	
99.9	area %
223.6-226.2	°C
0.2	%
01.Aug.2012	

**3. Advice and Remarks**

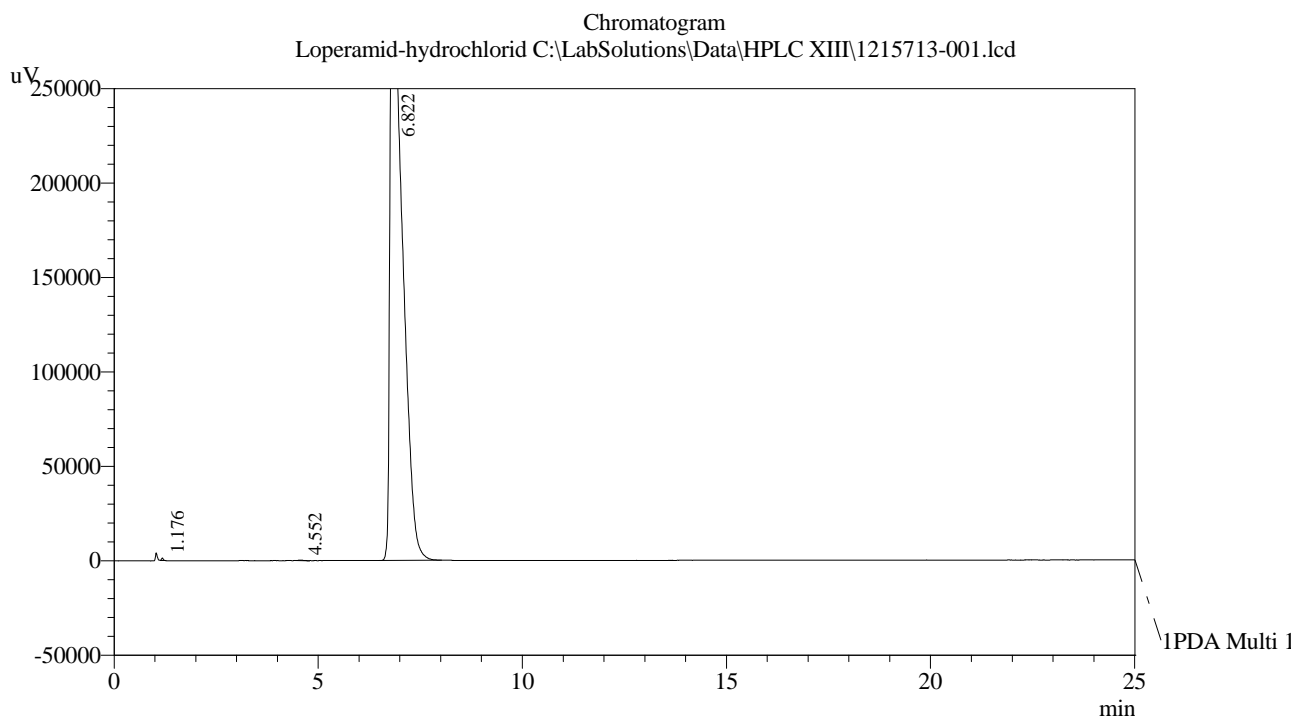
- The minimum shelf life is based on the current knowledge and holds only for proper storage conditions in the originally closed flasks/ packages.
- Whenever the container is opened for removal of aliquot portions of the substance, the person handling the substance must assure, that the integrity of the substance is maintained and proper records of all its handlings are kept. Special care has to be taken to avoid any contamination or adulteration of the substance.
- We herewith confirm that the delivery is effected according to the technical delivery conditions agreed.
- Particular properties of the products or the suitability for a particular area of application are not assured.
- We guarantee a proper quality within our General Conditions of Sales.

Sigma-Aldrich Laborchemikalien GmbH  
Quality Management SA-LC

# HPLC-Method

Article : Loperamide hydrochloride  
Article-No : 34014  
Batch : SZBC200XV

Column : L=150mm, ID=4,6mm; Discovery HS-C18 5µm  
Eluent : 50 % Acetonitrile  
50 % Water + 0,36% TMAOH\*5H2O, pH2,5  
Flow : 1,4ml/min  
Detector : UV-220nm  
Injection-Volume : 20µl  
Sample-Preparation : 0,2mg/ml Eluent  
Linearity : checked  
Evaluation : Normalisation (uncorrected)  
Operator : Schowe



1 PDA Multi 1 / 220nm 4nm

PeakTable

PDA Ch1 220nm 4nm

Peak#	Ret. Time	Area	Area %
1	1.176	3788	0.056
2	4.552	2562	0.038
3	6.822	6752078	99.906
Total		6758428	100.000