

Bundesanstalt für Materialforschung und -prüfung (BAM)

in cooperation with the International Commission on Glass (ICG)

## Certified Reference Material

### BAM-S053

Hydrolytic Resistance of Borosilicate Glass,  
glass grains tests (ISO 720, USP<660>, Ph.Eur. 3.2.1, ISO 719)

#### Certified Values

Acid consumption according to	Consumption of 0.02M HCl per g <sup>1)</sup> in mL	Uncertainty <sup>2)</sup> in mL
ISO 720	0.0422	0.0030
USP<660>	0.0428	0.0025
Ph.Eur. 3.2.1	0.0429	0.0026

<sup>1)</sup> Unweighted mean value of the means of 11 accepted sets of data (consisting of 3 to 6 single results), each set being obtained by a different laboratory.

<sup>2)</sup> Estimated expanded uncertainty  $U$  with a coverage factor of  $k = 2$ , corresponding to a level of confidence of approx. 95 %, as defined in the Guide to the Expression of Uncertainty in Measurement, (GUM, ISO/IEC Guide 98-3:2008).

This certificate is valid until 02/2044.

#### Values for information

Acid consumption according to	Consumption of 0.01M HCl per g <sup>1)</sup> in mL	Uncertainty <sup>2)</sup> in mL
ISO 719	0.036	0.006

<sup>1)</sup> Values were not certified, but given for information, because the spread of results was too high and homogeneity data was available only for a sample intake of 10 g (required sample intake for ISO 719: 2 g).

<sup>2)</sup> Estimated expanded uncertainty  $U$  with a coverage factor of  $k = 2$ , corresponding to a level of confidence of approx. 95 %, calculated from the uncertainties of the certified values.

#### Sample Description

The Reference Material is available in the form of glass rods (length: 185 mm, diameter: 9 mm, weight per rod: 27.5 g). It is supplied in boxes containing ca. 2 kg of material.

#### Recommended Use

The CRM is intended for quality control. According to ISO 719 the minimum sample intake is 2 g. For USP<660>, Ph.Eur. 3.2.1, and ISO 720 a minimum sample intake of 10 g is required.

#### Instructions for Use

Before use, the surface of the material should be cleaned carefully.

## Means of Accepted Data Sets

Certified values  
Consumption of 0.02M HCl per g in mL (ISO 719: 0.01M HCl)

Values for information

Line No.	ISO 720	USP<660>	Ph. Eur. 3.2.1	ISO 719
1	0.0363	0.0378	0.0372	0.0143
2	0.0377	0.0385	0.0402	0.0217
3	0.0390	0.0403	0.0407	0.0297
4	0.0399	0.0412	0.0408	0.0300
5	0.0407	0.0420	0.0412	0.0342
6	0.0408	0.0433	0.0428	0.0363
7	0.0435	0.0443	0.0433	0.0368
8	0.0445	0.0445	0.0447	0.0398
9	0.0448	0.0448	0.0448	0.0417
10	0.0460	0.0467	0.0468	0.0427
11	0.0505	0.0472	0.0488	0.0433
12				0.0510
13				0.0523
14				---
15				
<i>M</i>	0.0422	0.0428	0.0429	0.0356
<i>s<sub>M</sub></i>	0.0041	0.0031	0.0033	0.0109
$\bar{s}_i$	0.0017	0.0015	0.0016	0.0050

The laboratory mean values have been examined statistically to eliminate outlying values. Where a " --- " appears in the table it indicates that an outlying value has been omitted (technical or statistical). A data set consists of 3 to 6 single values of one laboratory.

*M* : mean of laboratory means

*s<sub>M</sub>* : standard deviation of laboratory means

$\bar{s}_i$  : averaged repeatability standard deviation (square root of the mean of laboratory variances)

## Participating Laboratories

Ardagh Glass GmbH, Nienburg, Germany

Cetim Grand Est, Schiltigheim, France

Corning European Technology Center (CETC), S&T European Laboratory, Fontainebleau, France

Corning Pharmaceutical Technology, NY, United States of America

Dorfner Anzaplan GmbH, Hirschau, Germany

Fraunhofer-Institut für Silicatforschung, Würzburg, Germany

Glass Technology Services Ltd, Sheffield, South Yorkshire, United Kingdom

NSG, Lathom, United Kingdom

Schott AG, Mainz, Germany

Schott AG, Analytical Services, Mitterteich, Germany

SG Lab Analytics, Stevanato Group S.p.A., Padova, Italy

Stazione Sperimentale del Vetro, Murano, Italy

T. Şişe ve Cam Fab. A.Ş. Science and Technology Center, Gebze Kocaeli, Turkey

TU Bergakademie Freiberg, Institut für Keramik, Glas- und Baustofftechnik, Freiberg, Germany

Zentrum für Glas- und Umweltanalytik GmbH, Ilmenau, Germany

## Transport and Storage

The material should be stored in a dry and clean environment at room temperature. Transport under normal ambient conditions.

## Metrological Traceability

The ensure traceable of the certified mass fractions to the SI (Système International d'Unités) the acid used for titration was measured against pure substances for establishing the titration factor.

## Technical Report

A detailed technical report describing the analysis procedures and the treatment of the analytical data used to certify BAM-S053 is available on request or can be downloaded from BAM website ([www.bam.de](http://www.bam.de)).

## Literature

- [1] ISO 720:1985, Glass - Hydrolytic resistance of glass grains at 121 degrees C -- Method of test and classification
- [2] The United States Pharmacopeia USP 41 NF36 First Supplement; <660> Containers - Glass: Hydrolytic Resistance, Glass Grains Test - 2018-08
- [3] EUROPEAN PHARMACOPOEIA 9.5. 3.2.1. Glass containers for pharmaceutical use, Hydrolytic resistance, Test B: Glass Grains Test; 2018-07
- [4] ISO 719:1985, Glass - Hydrolytic resistance of glass grains at 98 degrees C -- Method of test and classification

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**Bundesanstalt für Materialforschung und -prüfung (BAM)**

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