

Glass rods for the determination of hydrolytic resistance of borosilicate glass according to ISO 720, USP<660> and Ph.Eur. 3.2.1

| | |
|-----------------|-----------------------------------|
| Art. ID | BAM-S053 |
| Unit | 2000 g |
| Deliverydetails | No Dangerous Good /not restricted |

Description

Hydrolytic resistance is especially important for the manufacture of glass pharmaceutical primary packaging, since most medicines are preserved in a watery solution. In the international Pharmacopoeias PhEur and USP (Ph Eur = Pharmacopoea Europaea and USP = United States Pharmacopeia) the glass types used in manufacturing are split into water-resistance class Type I (highest resistance) to Type III. ISO 719 and 720 and the international Pharmacopoeias PhEur and USP describe analytical methods for the determination of hydrolytic resistance (glass-grain test). The new certified reference material BAM-S053 replaces the CRM NIST SRM 623 which is no longer available. Certification was done in an international certification round robin in cooperation with the international commission on glass (ICG) and the working group "lass analysis" of the Deutsche Glastechnische Gesellschaft e.V. (DGG). In total 15 laboratories from industry and research participated in the certification interlaboratory comparison. Certified values are given for the hydrolytic resistance according to ISO 720, USP<660> and Ph.Eur /// An informative value for hydrolytic resistance according to ISO 719 is given /// CRM BAM-S053 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.

| Text/Information | Analyte/Parameter | CAS number | Concentration/Value | Unit | Method | Source |
|------------------|--|------------|---------------------|------|--------|--------|
| | Acid consumption according to ISO 720 | | 0,0422 ± 0,003 | | | |
| | Acid consumption according to USP <660> | | 0,0428 ± 0,0024 | | | |
| | Acid consumption according to USP Ph.Eur. 3.2. | | 0,0429 ± 0,0026 | | | |
| | 1 | | | | | |