

## **Product information: Volumetric Instruments according to USP Requirements**

Companies producing pharmaceutical products for the USA market are therefore supervised by US authorities, e.g., the **FDA** (**F**ood and **D**rug **A**dministration) and have to meet the requirements of the **USP** (**U**nited **S**tates **P**harmacopoeia).

The current USP describes in section 31, that for glass volumetric instruments the Class A error limits described in the ASTM standards are required and list those for volumetric flasks, transfer pipettes and burettes in tables. For graduated pipettes up to and including 10 ml size the error limits are mentioned in the text.

BRAND volumetric instruments are produced according to the current DIN EN ISO standards. As the construction specifications are differently defined in the DIN EN ISO and ASTM standards, the error limits differ as well.

BRAND confirms for the delivered USP – volumetric instruments with the included USP - Certificates that the Class A error limits according to the ASTM standards are met.

### **BLAUBRAND® volumetric instruments with USP certificate**

Every glass volumetric measuring instrument is individually calibrated. Computer-controlled systems ensure maximum precision in a fully automated production line. The final step of this Statistical Process Control is random finished product sampling according to DIN ISO 3951. The quality management system applied at BRAND and certified to DIN EN ISO 9001 is a combination of process monitoring and random checks. The accepted quality level is at the very least 0.4.

#### **USP - Batch certificate for volumetric flasks only\***

Each volumetric flask is supplied with one batch certificate per packing of the manufacturer confirming the ASTM Class A error limits required by USP. The certificate records the mean volume, the standard deviation of the batch and the date of issue (batch number: year of manufacture/batch).

#### **USP - Individual certificate for all volumetric instruments\***

The Volumetric measuring instrument is supplied with an individual certificate confirming the ASTM Class A error limits required by USP. The certificate records the measured volume, the uncertainty of measurement and the date of issue (individual serial number: year of manufacture/batch/consecutive instrument number).

\* For wide neck flasks no USP certificates are possible

### **Appendix: Table of tolerances**

**USP Chapter <31> Volumetric Apparatus referring to ASTM error margins.  
USP Certificates are confirming the ASTM error margins**

<b>Instrument</b>	<b>ml Vol.</b>	<b>Error Limit 'A' in ml DIN EN ISO 1042</b>	<b>Error Limit 'A' in ml ASTM E 288</b>	<b>Individual Certificate</b>	<b>Batch Certificate</b>
Volumetric flask	5	± 0.025	± 0.020	<b>USP</b>	<b>USP</b>
Volumetric flask	10	± 0.025	± 0.020	<b>USP</b>	<b>USP</b>
Volumetric flask	25	± 0.04	± 0.03	<b>USP</b>	<b>USP</b>
Volumetric flask	50	± 0.06	± 0.05	<b>USP</b>	<b>USP</b>
Volumetric flask	100	± 0.10	± 0.08	<b>USP</b>	<b>USP</b>
Volumetric flask	200	± 0.15	± 0.10	<b>USP</b>	<b>USP</b>
Volumetric flask	250	± 0.15	± 0.12	<b>USP</b>	<b>USP</b>
Volumetric flask	500	± 0.25	± 0.20	<b>USP</b>	<b>USP</b>
Volumetric flask	1000	± 0.40	± 0.30	<b>USP</b>	<b>USP</b>
Volumetric flask	2000	± 0.60	± 0.50	<b>USP</b>	<b>USP</b>
<b>Instrument</b>	<b>ml Vol.</b>	<b>Error Limit 'A' in ml DIN EN ISO 648</b>	<b>Error Limit 'A' in ml ASTM E 969</b>	<b>Individual Certificate</b>	<b>Batch Certificate</b>
Transfer Pipet, one mark	0,5	± 0,005	± 0,006	<b>USP</b>	not possible
Transfer Pipet, one mark	1	± 0,008	± 0,006	<b>USP</b>	not possible
Transfer Pipet, one mark	2	± 0,010	± 0,006	<b>USP</b>	not possible
Transfer Pipet, one mark	3	± 0,010	± 0,01	<b>USP</b>	not possible
Transfer Pipet, one mark	4	± 0,015	± 0,01	<b>USP</b>	not possible
Transfer Pipet, one mark	5	± 0,015	± 0,01	<b>USP</b>	not possible
Transfer Pipet, one mark	6	± 0,015	± 0,01	<b>USP</b>	not possible
Transfer Pipet, one mark	7	± 0,015	± 0,01	<b>USP</b>	not possible
Transfer Pipet, one mark	8	± 0,02	± 0,02	<b>USP</b>	not possible
Transfer Pipet, one mark	9	± 0,02	± 0,02	<b>USP</b>	not possible
Transfer Pipet, one mark	10	± 0,02	± 0,02	<b>USP</b>	not possible
Transfer Pipet, one mark	15	± 0,03	± 0,03	<b>USP</b>	not possible
Transfer Pipet, one mark	20	± 0,03	± 0,03	<b>USP</b>	not possible
Transfer Pipet, one mark	25	± 0,03	± 0,03	<b>USP</b>	not possible
Transfer Pipet, one mark	30	± 0,03	± 0,03	<b>USP</b>	not possible
Transfer Pipet, one mark	40	± 0,05	± 0,05	<b>USP</b>	not possible
Transfer Pipet, one mark	50	± 0,05	± 0,05	<b>USP</b>	not possible
Transfer Pipet, one mark	100	± 0,08	± 0,08	<b>USP</b>	not possible
<b>Instrument</b>	<b>ml Vol.</b>	<b>Error Limit 'A' in ml DIN EN ISO 835</b>	<b>Error Limit 'A' in ml ASTM E 1293</b>	<b>Individual Certificate</b>	<b>Batch Certificate</b>
Graduated Pipet	1	± 0.007	± 0.01	<b>USP</b>	not possible
Graduated Pipet	2	± 0.010	± 0.01	<b>USP</b>	not possible
Graduated Pipet	5	± 0.030	± 0.02	<b>USP</b>	not possible
Graduated Pipet	10	± 0.05	± 0.03	<b>USP</b>	not possible
<b>Instrument</b>	<b>ml Vol.</b>	<b>Error Limit 'A' in ml DIN EN ISO 385</b>	<b>Error Limit 'A' in ml ASTM E 1189* / E 287</b>	<b>Individual Certificate</b>	<b>Batch Certificate</b>
Buret / Subdiv. 0,02	10	± 0.02	± 0.02*	<b>USP</b>	not possible
Buret / Subdiv. 0,1	25	± 0.03	± 0.03	<b>USP</b>	not possible
Buret / Subdiv. 0,1	50	± 0.05	± 0.05	<b>USP</b>	not possible
<b>Instrument</b>	<b>ml Vol.</b>	<b>Error Limit 'A' in ml DIN EN ISO 835</b>	<b>Error Limit 'A' in ml ASTM E 1272</b>	<b>Individual Certificate</b>	<b>Batch Certificate</b>
Measuring cylinder	5	± 0.05	± 0.05	<b>ASTM</b>	not possible
Measuring cylinder	10	± 0.10	± 0.10	<b>ASTM</b>	not possible
Measuring cylinder	25	± 0.25	± 0.17	<b>ASTM</b>	not possible
Measuring cylinder	50	± 0.5	± 0.25	<b>ASTM</b>	not possible
Measuring cylinder	100	± 0.5	± 0.50	<b>ASTM</b>	not possible
Measuring cylinder	250	± 1.0	± 1.00	<b>ASTM</b>	not possible
Measuring cylinder	500	± 2.5	± 2.0	<b>ASTM</b>	not possible
Measuring cylinder	1000	± 5	± 3.0	<b>ASTM</b>	not possible
Measuring cylinder	2000	± 10	± 6.0	<b>ASTM</b>	not possible