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Product information: Volumetric Instruments according to USP Requirements

Companies producing pharmaceutical products for the US market are supervised by US authorities, e.g. the **FDA (Food and Drug Administration)**, and have to meet the requirements of the **USP (United States Pharmacopeia)**.

The current USP prescribes in section 31 the use of volumetric instruments with accuracy in accordance to Class A of the ASTM standards 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 manufactured 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.

With included USP certificates BRAND confirms for the delivered USP-volumetric instruments that the class A error limits according to the USP or, rather, 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 sampling of finished product according to DIN ISO 3951.

The quality management system applied at BRAND, which is certified according to DIN EN ISO 9001, is a combination of process monitoring and random checks with an accepted quality level (AQL) of about 0.4.

USP-Batch certificate

The batch certificate confirms that ASTM Class A error limits required by USP are met. The certificate records the mean value, the standard deviation of the batch and the date of issue (batch number: year of manufacture/batch).

USP-Individual certificate

The individual certificate confirms that ASTM Class A error limits required by USP are met. The certificate records the mean value, the uncertainty of measurement and the date of issue (individual serial number: year of manufacture/batch/consecutive instrument number).

Appendix: Table of tolerances and volumetric instruments available with USP certificates

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Volumetric Instrument	ml Vol.	Error Limit 'A' in ml DIN EN ISO 1042	Error Limit 'A' in ml ASTM E 288	Individual Certificate	Batch Certificate
Volumetric Flask	5	± 0,025	± 0,02	USP	USP
Volumetric Flask	10	± 0,025	± 0,02	USP	USP
Volumetric Flask	20	± 0,04	± 0,02	USP	USP
Volumetric Flask	25	± 0,04	± 0,03	USP	USP
Volumetric Flask	50	± 0,06	± 0,05	USP	USP
Volumetric Flask	100	± 0,10	± 0,08	USP	USP
Volumetric Flask	200	± 0,15	± 0,10	USP	USP
Volumetric Flask	250	± 0,15	± 0,12	USP	USP
Volumetric Flask	500	± 0,25	± 0,20	USP	USP
Volumetric Flask	1000	± 0,40	± 0,30	USP	USP
Volumetric Flask	2000	± 0,60	± 0,50	USP	USP
	ml Vol.	Error Limit 'A' in ml DIN EN ISO 648	Error Limit 'A' in ml ASTM E 969	Individual Certificate	Batch Certificate
Transfer Pipet, one mark	0,5	± 0,005	± 0,006	USP	USP
Transfer Pipet, one mark	1	± 0,008	± 0,006	USP	USP
Transfer Pipet, one mark	2	± 0,010	± 0,006	USP	USP
Transfer Pipet, one mark	3	± 0,010	± 0,01	USP	USP
Transfer Pipet, one mark	4	± 0,015	± 0,01	USP	USP
Transfer Pipet, one mark	5	± 0,015	± 0,01	USP	USP
Transfer Pipet, one mark	6	± 0,015	± 0,01	USP	USP
Transfer Pipet, one mark	7	± 0,015	± 0,01	USP	USP
Transfer Pipet, one mark	8	± 0,02	± 0,02	USP	USP
Transfer Pipet, one mark	9	± 0,02	± 0,02	USP	USP
Transfer Pipet, one mark	10	± 0,02	± 0,02	USP	USP
Transfer Pipet, one mark	15	± 0,03	± 0,03	USP	USP
Transfer Pipet, one mark	20	± 0,03	± 0,03	USP	USP
Transfer Pipet, one mark	25	± 0,03	± 0,03	USP	USP
Transfer Pipet, one mark	30	± 0,03	± 0,03	USP	USP
Transfer Pipet, one mark	40	± 0,05	± 0,05	USP	USP
Transfer Pipet, one mark	50	± 0,05	± 0,05	USP	USP
Transfer Pipet, one mark	100	± 0,08	± 0,08	USP	USP
	ml Vol.	Error Limit 'A' in ml DIN EN ISO 835	Error Limit 'A' in ml ASTM E 1293	Individual Certificate	Batch Certificate
Graduated Pipet / Subdiv. 0,01	1	± 0,007	± 0,01	USP	USP
Graduated Pipet / Subdiv. 0,02	2	± 0,010	± 0,01	USP	USP
Graduated Pipet / Subdiv. 0,05	5	± 0,030	± 0,02	USP	USP
Graduated Pipet / Subdiv. 0,1	10	± 0,05	± 0,03	USP	USP
	ml Vol.	Error Limit 'A' in ml DIN EN ISO 385	Error Limit 'A' in ml ASTM E 1189 / E 287	Individual Certificate	Batch Certificate
Buret / Subdiv. 0,01	2	± 0,01	± 0,01	USP	
Buret / Subdiv. 0,01	5	± 0,01	± 0,01	USP	
Buret / Subdiv. 0,02	10	± 0,02	± 0,02	USP	
Buret / Subdiv. 0,05	25	± 0,03	± 0,03	USP	
Buret / Subdiv. 0,1	50	± 0,05	± 0,05	USP	
	ml Vol.	Error Limit 'A' in ml DIN EN ISO 4788	Error Limit 'A' in ml ASTM E 1272	Individual Certificate	Batch Certificate
Measuring Cylinder / Subdiv. 0,1	5	± 0,05	± 0,05	USP	USP
Measuring Cylinder / Subdiv. 0,2	10	± 0,10	± 0,10	USP	USP
Measuring Cylinder / Subdiv. 0,5	25	± 0,25	± 0,17	USP	USP
Measuring Cylinder / Subdiv. 1	50	± 0,5	± 0,25	USP	USP
Measuring Cylinder / Subdiv. 1	100	± 0,5	± 0,50	USP	USP
Measuring Cylinder / Subdiv. 2	250	± 1,0	± 1,0	USP	USP
Measuring Cylinder / Subdiv. 5	500	± 2,5	± 2,0	USP	USP
Measuring Cylinder / Subdiv. 10	1000	± 5	± 3,0	USP	USP
Measuring Cylinder / Subdiv. 20	2000	± 10	± 6,0	USP	USP