VITLAB® Dispenser

Standard Operating Procedure (SOP)

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1. Introduction

The standard DIN EN ISO 8655 describes both the design and testing of bottletop dispensers. The following instructions describe how to apply the ISO standard in practice.

We recommend a testing of the dispensers every 3 - 12 month. This interval may be adjusted to individual requirements. For example, when working very frequently or when using aggressive media, the dispensers should be tested more often.

These instructions may also be used as a basis for the supervision of testing devices according to DIN EN ISO 9001, DIN EN ISO 10012 and DIN EN ISO / IEC 17025.

For the regular examinations required by DIN EN ISO 9001, DIN EN ISO 10012 and DIN EN ISO / IEC 17025 and the GLP guidelines, VITLAB additionally provides an optimized calibration service acc. to ISO 8655. For more detailed information contact us or your labware supplier.

2. Preparation of the dispensers for testing

2.1 Instrument identification

Read instrument type and nominal capacity	► Enter in test record
Read serial number (located at the valve head)	► Enter number in test record
Read customers identification, if present	► Enter identification in test record

2.2 Minimum configuration for dispenser VITLAB® genius and simplex

Have the operation manual ready	
VITLAB® genius resp. simplex	► Use only manufacturer's original spare parts
Telescopic intake tube	
Discharge tube	
Tool	

2.3 Cleaning

Rinse instrument with suitable cleaning solution	► Select suitable cleaning solution according to the medium which was used
Then rinse the instrument again several times with distilled water	► See operating manual, page 10 ff.

2.4 Visual examination for damage or leakage

Examine the device for scratches or other mechanical damages	► Enter result in test record
Intake or discharge tube bent or damaged	► Possible safety risk! Replace damaged parts (see operating manual „Accessoires and spare parts")
Leakage, possibly caused by mechanically damaged connections	► Possible safety risk! Replace damaged parts or return instrument for repair

3. Functional testing

Mount telescopic intake tube

Screw the dispenser on a bottle with distilled or deionized water

Prime dispenser (see operating manual page 20)

► A few bubbles up to 1 mm in the glass cylinder are permissible

During priming, check if the piston moves smoothly

► If the piston moves stiffly, clean immediately (see operating manual page 22)

If there is a malfunction of the instrument (e. g. piston is hard to move, sticky valves or leakage) follow the steps described in the „Troubleshooting" section of the operating manual.

4. Test instruments and environment

Test room

The testing should be performed in a draught-free room with constant temperature and humidity.

Temperature

The test dispenser and the test liquid must be at equilibrium with the room temperature. For this, leave the dispenser (without the packaging) and the test liquid for at least 1 hour in the test room. Try to avoid temperature changes (e. g. from sun radiation). Then carry out a comparison between room, liquid and dispenser temperature.

Test liquid

Distilled or deionized water (bottle min. 500 ml) of a minimum quality 3 according to ISO 3969. The maximum difference of room and water temperature should be 0.5 °C.

Recipient vessel

Vessel (e. g. Erlenmeyer flask) filled with water to a level that the bottom is completely covered.

Thermometer

Use only thermometers with a maximum measurement error of 0.2 °C.

Balance

Recommended specifications, see table:

Selected volume* of the device to be tested V	Resolution of the balance display mg	Repeatability and linearity mg	Standard uncertainty µl
50 µl < V ≤ 1000 µl	0.1	0.2	0.2
1 ml < V ≤ 10 ml	0.1	0.2	0.2
10 ml < V ≤ 100 ml	1	2	2

*For practical purposes, the nominal volume may be used to choose the balance

Traceability of test results to national standards

Through the use of calibrated testing devices (balance and thermometer), the requirement of DIN EN ISO 9001, DIN EN ISO 10012 and DIN EN ISO / IEC 17025 to refer the test to national standards is fulfilled. The calibration of the balance e. g. can be carried out either by a DAkkS calibration or official certification of the balance, or by calibrating the balance with appropriate weights that are traced to the national standard. The calibration of the thermometer, hygrometer and barometer can also be carried out by DAkkS calibration or official certification, or by a comparison with thermometers that are traced to the national standard (under defined conditions).

5. Gravimetric testing

1. Determine temperature of the test liquid.
   ▶ Enter temperature into test record.
2. Set the nominal volume (only variable volume dispensers).
3. Dispense some liquid into a separate vessel. Wipe off the drop on the discharge tube against the wall of the vessel.
4. Place the recipient vessel on the balance and tare.
5. Place recipient vessel under the discharge tube.
6. Pull the piston to the uppermost stop.
   ▶ Slow and steady movement.
7. Push the piston down to the undermost stop.
   ▶ Slow and steady movement.
8. Wipe off the discharge tube at the vessel wall.
9. Place the recipient vessel on the balance and record the value.
   ▶ Enter weighing value in test record.
10. Tare balance.
11. Repeat steps 2 - 10 a total of ten times.
12. Subsequently dispense ten times each 50% resp. 10% of the nominal volume and enter the values in the test record.

6. Evaluation of the results of the gravimetric test

The obtained weighing values from the gravimetric test are only the mass values of the dispensed volume without the correction of the air buoyancy. To obtain the actual volume, a correction calculation taking into account the water density and the air buoyancy has to be carried out.

The following calculations have to be carried out:

Mean weighing values
Example for 10 weighing values:

$$\bar{x} = \frac{x_1 + x_2 + x_3 \ldots + x_{10}}{10}$$

Mean volume

$$\bar{V} = \bar{x} \cdot Z$$

- Factor z; see table
- Enter value in test record

Standard deviation volume

$$s = Z \cdot \sqrt{\frac{(x_1 - \bar{x})^2 + (x_2 - \bar{x})^2 + (x_3 - \bar{x})^2 + \ldots + (x_{10} - \bar{x})^2}{9}}$$

- Factor z; see table
- Enter value in test record

Accuracy

$$A\,[\%] = \frac{\bar{V} - V_0}{V_0} \cdot 100$$

- Enter value in test record

Coefficient of variation

$$CV\% = \frac{100\ s}{\bar{V}}$$

- Enter value in test record

Comparison actual values - nominal values
Error limits: see tables 7.2.1 and 7.2.2 or definition of individual error limits.

Result

If the calculated values for A [%] and CV [%] are smaller than or equal the error limits, the dispenser is in good working order.

If the calculated values are **larger** than the error limits:
- Verify, if all above instructions have been carefully followed step by step.
- Observe notes from the „Troubleshooting" section.
- Recalibrate the dispenser according to the steps in the operating manual.

If these measures are not successful, we recommend to make use of the VITLAB calibration service.

Possible volume errors and the resulting measures

Error	Possible causes	Measures
Volume too large	Drop remains before dispensing at the discharge tube.	▶ Before weighing, wipe off any drop into recipient vessel. Tare balance.
	Jerky dispensing.	▶ Dispense with smooth and steady movement.
	During filling, a drop already was released.	▶ Move the piston cautiously to the upper stop.
Volume too small	Drop still remains on the discharge tube after dispensing.	▶ Before weighing, wipe off drop into recipient vessel.
	Device leaking.	▶ Repeat functional test. Retighten or replace valves. Intake and discharge tube must be mounted properly.
	Air bubbles in the dispenser.	▶ Dispenser needs to be primed.
Other causes	Uneven dispensing.	▶ Use smooth and gentle movements to operate the piston upwards and downwards. Approach the upper and lower stop slowly, so that no drops are released from the discharge tube.
	Temperature adjustment between room, instrument and water temperature not completed.	▶ Carry out temperature adjustment.

7. Tables

7.1 Factor z - Excerpt from DIN EN ISO 8655, Part 5.
Table refers to 1013 hPa. Valid from 980 - 1040 hPa.

Temperature °C	Factor z ml / g	Temperature °C	Factor z ml / g
15	1.0020	23	1.0035
15.5	1.0020	23.5	1.0036
16	1.0021	24	1.0038
16.5	1.0022	24.5	1.0039
17	1.0023	25	1.0040
17.5	1.0024	25.5	1.0041
18	1.0025	26	1.0043
18.5	1.0026	26.5	1.0044
19	1.0027	27	1.0045
19.5	1.0028	27.5	1.0047
20	1.0029	28	1.0048
20.5	1.0030	28.5	1.0050
21	1.0031	29	1.0051
21.5	1.0032	29.5	1.0052
22	1.0033	30	1.0054
22.5	1.0034		

7.2 Error limits for VITLAB® Dispensers

The stated error limits for the VITLAB® Dispensers (Tabelle 7.2.2) are final test values relative to the nominal capacity. These error limits refer to new instruments under optimised test conditions (qualified operators and standardised ambience conditions).

Table 7.2.1: Excerpt from DIN EN ISO 8655, Part 5.

Nominal volume	A		CV	
ml	± %	± µl	%	µl
1	0.6	6	0.2	2
2	0.6	12	0.2	4
5	0.6	30	0.2	10
10	0.6	60	0.2	20
25	0.6	150	0.2	50
50	0.6	300	0.2	100
100	0.6	600	0.2	200

Table 7.2.2: Values from operating manual for VITLAB® genius, simplex und TA

Nominal volume ml	A ≤ ± %	CV ≤ %
2.5	0.6	0.1
1.25	1.2	0.2
0.25	6	1
5	0.5	0.1
2.5	1.0	0.2
0.5	5	1
10	0.5	0.1
5	1.0	0.2
1	5	1
25	0.5	0.1
12.5	1.0	0.2
2.5	5	1
50	0.5	0.1
25	1.0	0.2
5	5	1
100	0.5	0.1
50	1.0	0.2
10	5	1
simplex fix		
1	0.6	0.1
5	0.5	0.1
10	0.5	0.1

For calibration, the error limits observed by the operator must be individually defined by the user. For this purpose, the following methods can be applied:

- If required by the application and if the optimised conditions are present, the stated error limits can also be expected in the case of used volumetric instruments are in good working order.
- In analogy to the German regulations for official testing, it is also admissable to apply limits which are typical for practice. These practice limits correspond to double the limits for official testing. In this case, the values in table 7.2.2. should be doubled!
- The user may also define his own individual tolerance limits corresponding to his particular application, and apply these error limits for the calibration of the instrument.

The above procedures fulfil the requirements of DIN EN ISO 9001, DIN EN ISO 10012 and DIN EN ISO / IEC 17025.

Test record for volumetric instruments

1. Device:
- ❑ VITLAB® continuous E / RS
- ❑ VITLAB® genius
- ❑ VITLAB® simplex
- ❑ VITLAB® TA
- ❑ VITLAB® micropipette
- ❑ _____

Typ:
- ❑ analog
- ❑ fix

Nominal volume: _____
Serial number: _____
Customers identification: _____

2. Damage:
- ❑ none
- ❑ Type of damage
  .....
  .....
  .....
- ❑ Damage repaired

3. Functional defects:
- ❑ none
- ❑ Type of functional defect
  .....
  .....
  .....
- ❑ Functional defect repaired

4. Water temperature:.....°C
Balance:.....
Thermometer:.....

Air pressure: .....
Relative Humidity: (minimum 35%):.....
Correction factor Z: .....

5. Weighing values and results of the gravimetric test:

Weighing value No.	Nominal capacity	50 %	10 %
x_1			
x_2			
x_3			
x_4			
x_5			
x_6			
x_7			
x_8			
x_9			
x_{10}			

6. Evaluation of the gravimetric test:

Calculated values		Nominal capacity	50 %	10 %
a	$\overline{V}$			
b	s			
c	A [%] found			
d	CV [%] found			
e	A [%] nominal			
f	VK [%] nominal			
g	Result			

The test was carried out according to DIN EN ISO 8655.

Date _____ Signature _____

VITLAB®

Declaration on the Abscence of Health Hazards

To be sent together with the instrument or via mail (if urgent with fax **in advance**).

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We intend to give our staff a maximum of protection from health hazards caused by contaminated instruments. We therefore ask for your understanding that we cannot carry out any calibration or repair unless this declaration is submitted completed and signed.

For consignment dd. ..... **/ for delivery note No.** ..... **:**

The undersigned hereby declares:

- That the instruments have been carefully cleaned and decontaminated before shipment.
- That the instruments pose no danger through bacteriological, chemical, radiological or viral contamination
- That she / he is aware that shipment of contaminated instruments is a violation of the law, and she / he personally and the Institution represented may be held liable for any damages caused contaminated instruments.
- For calibration service only: minor repairs of a value up to € 50,- + VAT shall be carried out and invoiced without further queries. (Cross out if not applicable).

Company / Laboratory (Stamp)

Tel./Fax/E-Mail:

.....
Name

.....
Position

.....
Date, Signature

- In case of return for repair, please provide us with the following supplementary information:

  Detected defect:.....

  Media which the instrument has been used with: .....