

	Standard Operating Procedure Specific Gravity Determination using a Pycnometer		SOP Number D-737	Revision 5
			Effective Date 02/01/23	Page Page 1 of 4
Written by/ Date  01/30/23		Reviewed by/ Date SAS 01/30/23		Approved by/ Date  01/31/23
Title: QC Data Reviewer		Title: Analytical Development Scientist		Title: Quality Control Director

1.0 Purpose

The purpose of this procedure is to describe a method for specific gravity determination of finished products and raw materials using a pycnometer.

2.0 Scope

This procedure follows USP <841> Specific Gravity Method I guidelines and is designed specifically for measuring free flowing liquids.

3.0 Responsibility

- 3.1 It is the responsibility of QC and Analytical Chemists to follow this procedure.
- 3.2 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of QC Laboratory Management and/or Analytical Development to keep this procedure aligned with current practices.

4.0 Definitions

- 4.1 **STD** – Standard
- 4.2 **H₂O** – Millipore Water, 18.2Ω
- 4.3 **QC** – Quality Control
- 4.4 **CofA** – Certificate of Analysis

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5.0 References

- 5.1 USP <841> Specific Gravity, method I
- 5.2 D-737-F1, Form, Specific Gravity Test Ticket

6.0 Reagents and Equipment

- 6.1 Reagents
 - 6.1.1 H₂O- 18.2Ω Millipore Water
- 6.2 Equipment
 - 6.2.1 Analytical Scale
 - 6.2.2 25°C +/- 1°C Incubator
 - 6.2.3 1mL pipette
 - 6.2.4 200uL pipette
 - 6.2.5 10mL pipette
 - 6.2.6 Pycnometer
 - 6.2.7 Beaker

7.0 Procedure

- 7.1 Preparation
 - 7.1.1 Be sure to wear gloves during the course of the experiment as oils and dust on fingertips could influence the weight of the pycnometer.
 - 7.1.2 Select a scrupulously clean, dry pycnometer that has been previously calibrated by determining its weight.

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7.1.3 Boil an appropriate amount of Millipore water for the testing.

7.2 Standard Preparation and Measurement

7.2.1 Fill the pycnometer until the liquid level is just below the rim using recently boiled water cooled to room temperature (below 25°C). Avoid trapping air bubbles in the water.

7.2.2 Place the perforated lid on top of the cup and seal it with a careful twisting motion. An excess of liquid should ooze (not squirt) out of the small hole on top of the snugly fitting lid. Wipe off this excess water using a soft cloth or tissue paper.

7.2.3 Place filled pycnometer in a 25°C incubator for 15 minutes to equilibrate temperature

7.2.4 If it a temperature other than 25°C is specified the water and sample should be heated to that temperature.

7.2.5 Weigh the properly filled cup to the nearest 0.1 milligram and document the weight.

7.3 Sample Preparation and Measurement

7.3.1 Fill the pycnometer until the sample liquid level is just below the rim using sample liquid that is below 25°C. Avoid trapping air bubbles in the sample liquid.

7.3.2 Place the perforated lid on top of the cup and seal it with a careful twisting motion. An excess of liquid should ooze (not squirt) out of the small hole on top of the snugly fitting lid. Wipe off this excess liquid using a soft cloth or tissue paper or wash off if necessary by holding pycnometer so that rinse solvent or water does not enter small hole in lid. Dry using a cloth or tissue.

7.3.3 Place filled pycnometer in a 25°C incubator for 15 minutes to equilibrate temperature.

7.3.4 Weigh the properly filled cup to the nearest 0.1 milligram and document the weight.

7.4 Calculations

7.4.1 Use the calibration weight of the pycnometer that has been verified and subtract from the total weight of the standard and the sample.

$$7.4.1.1 \text{ Specific Gravity} = \frac{[(\text{weight of pyc} + \text{sample}) - \text{weight of pyc}]}{[(\text{weight of pyc} + \text{H}_2\text{O}) - \text{weight of pyc}]}$$

7.4.2 Determine a specific gravity of the liquid by calculating the quotient obtained by dividing the weight of the sample liquid contained in the pycnometer by the weight of the water contained in it, both determined at 25°C unless otherwise directed. Report to three decimal places.

7.5 Requirements

7.5.1 Utilize form D-737-F1 Specific Gravity Test Ticket to report specific gravity findings.

7.5.2 Requirements for specific gravity are met if the result is within the specified range given on the CofA or in the product profile.

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	08/01/13	New	13-0615	B. Johns
2	09/09/15	Biennial review: Updated SOP format.	15-0822	B. Johns
3	01/14/19	Scheduled review: updated SOP.	19-0038	J. Maignan
4	09/07/22	Scheduled review: updated SOP logo and format.	CC-22-0368	K. Burris
5	01/30/23	Updated to add reference to new form D-737-F1. Created new form D-737-F1 that can accept up to three tests per page.	CC-23-0052	J. Nicholson



Specific Gravity Determination Using a Pycnometer

Form: D-737-F1 CCR No: CC-23-0052 Revision: 0

SOP #: D-737

Balance ION #: _____ Cal due: _____

Date: _____

Thermometer ION #: _____ Cal due: _____

Paste Weigh Tapes Below

Profile ID:	Release Spec:	
Sample #:	Pycnometer (g):	Pycnometer + Sample (g):
Temp (C°):	Pycnometer + H2O (g):	Specific Gravity:

Profile ID:	Release Spec:	
Sample #:	Pycnometer (g):	Pycnometer + Sample (g):
Temp (C°):	Pycnometer + H2O (g):	Specific Gravity:

Profile ID:	Release Spec:	
Sample #:	Pycnometer (g):	Pycnometer + Sample (g):
Temp (C°):	Pycnometer + H2O (g):	Specific Gravity:

Performed By/Date

Reviewed By/Date