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1.0 Purpose

This SOP describes the procedure for measuring specific gravity using the Anton-Paar DMA 4100M.

2.0 Scope

This SOP applies to Process Analytics/Quality Control (PA/QC) and Technical Operations personnel who will be measuring specific gravity.

3.0 Authority and Responsibility

- 3.1 The Process Analytics/Quality Control (PA/QC) Technical Lead, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.
- 3.2 PA/QC or Technical Operations personnel are responsible for the performance of this procedure and documenting training on this procedure to Biopharmaceutical Quality Assurance (BQA).
- 3.3 PA/QC or Technical Operations is responsible for testing of the sample.
- 3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

4.0 Materials and Equipment

- 4.1 Anton Paar DMA 4100M Density Meter (BDP MEF #86490)
- 4.2 5 cc syringes, BDP PN 21804, or BDP approved equivalent
- 4.3 Type 1 water, or equivalent
- 4.4 Acetone, BDP PN 30324, Methanol, BDP PN 30853, or BDP approved equivalent


4.5 Waste Container

5.0 Measurement of Specific Gravity

5.1 The instrument should be left on continuously; to wake the unit, tap the screen and the screen will brighten.

5.2 Daily Checks

5.2.1 A density check with Type 1 water is required daily before the instrument can be used for any sample measurements.

5.2.2 From the home screen, press the  key in the upper left corner to expand the side menu. Select the **Check Execution** option. Select the **Water Check**. Press **Start**.

5.2.3 As directed, fill the measuring cell with water from a syringe by depressing the plunger on the syringe until water is seen flowing out of the cell and into the waste container. Leave the syringe on the instrument and press **OK** to start the check.

5.2.4 The instrument will perform a check and the results will be displayed once complete. If the check passed, the instrument is now ready for use. If the check did not pass, follow the on-screen instructions or consult the manual to adjust the instrument as necessary. If the check still does not pass, the instrument may not be used until serviced.

5.2.5 Press **Home** to return to the home screen.

5.3 Measuring Samples

5.3.1 Confirm the Method shown in the top bar of the screen is "Density @ 15.56°C".


5.3.1.1 If a different method is shown, press the **Method** button at the bottom of the screen and select Density @ 15.56°C, then press **OK**.

5.3.2 Press **Start** to begin a new sample.

5.3.3 The instrument will require a sample name and a QC number. Press the text box beside each line on the screen that appears to enter the required information. If there are more than one sample to be analyzed for a QC#, the QC# should be amended with a -1, -2, etc., for each sample.


5.3.4 Fill a syringe with sample, remove air bubbles, and inject \approx 3 - 4 mL into the inlet and leave the syringe in place.

5.3.5 Press **Start**, the unit will now analyze the sample. The measuring cell can be observed on the camera shown on the screen and the test progress can be monitored by the status bar.

5.3.6 Once the sample is complete the result will be shown on the screen. To print the report, press the  key in the upper left corner to expand the side menu. Select **Measured Data**. Select the desired sample and then press the **Details** button. A window will open showing the details of the selected sample. Press the **Print or Export** button. Select the **Print Report (Paper/PDF File)** option and press **OK**. The default printer should be shown, press **OK**. Once the printing has finished, press the **OK** button to acknowledge. Press **Home** to return to the sample screen.

5.3.7 For additional samples, repeat section 5.3.2-5.3.6.

5.3.8 When finished, flush the cell with acetone or methanol, then press the air pump

button  to dry the cell. The pump is programmed to run for 5 minutes and shut off automatically. The instrument will go into screen saver mode after a period of inactivity.

6.0 Documentation

- 6.1 Record use, preventive maintenance, standardization/calibration of the instrument, density check results, and QC numbers in the equipment logbook as per **SOP 21531 - Equipment Logs**.
- 6.2 The instrument stores completed test data for the 1000 most recent tests. This data may be retrieved later and reprinted if necessary. The files are non-editable.
- 6.3 Annotate the report from 5.3.6 with the equipment MEF# and PM due date, then attach the report to QC Test Request Form 22002-01.

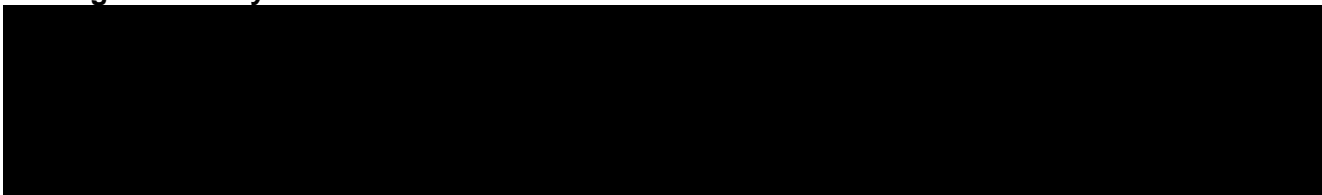
7.0 References and Related Documents

SOP 21531 *Equipment Logs*

8.0 Attachments

8.1 **Sample Report**

9.0 Change Summary





Attachment
Sample Report

BDP
8560 Progress Dr
Frederick, MD 21702
US



Anton Paar DMA™ 4100 M - Measurement Results:

Software version: 2.93.11553.547
DMA™ Density serial number: 82621667
Lovis serial number: 82639426
Abbatemat serial number: 99035068

Sample Information:

- ▶ Unique Sample Id: 8
- ▶ Date: 11/8/2018
- ▶ Time: 10:38:33 AM
- ▶ Sample Name: water
- ▶ QC#: XXXXXX
- ▶ Master Condition: valid

Measurement Result:

- ▶ Density: 0.9990 g/cm³
- ▶ Specific Gravity: 1.000
- ▶ Density Temperature: 15.56 °C