1.0 Purpose

The purpose of this procedure is to establish a maintenance program for the Titrette Bottle-Top Burette used for USP analysis. This procedure will help to insure compliance with 21 CFR 211.67 'Equipment Cleaning and Maintenance'.

2.0 Scope

This procedure applies to the USP bottle-top burette (S/N: 08L62300). Maintenance will be performed on the bottle-top burette by QA Lab personnel every 8 weeks or any time a drop in performance is noted.

3.0 Responsibility

QA Lab personnel are responsible for performing this procedure.

4.0 Safety Considerations

Appropriate PPE should be worn at all times including but not limited to steel-toed shoes, gloves (nitrile or latex), safety glasses, and a lab coat.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

- Brand Titrette® bottle-top burette
- Bottle (at least 500 ml) filled with deionized water
- Receiving vessel (e.g., Erlenmeyer flask) with bottom of vessel covered with deionized water
- Nitrile gloves
- Laboratory tissue wipers

6.0 Procedure

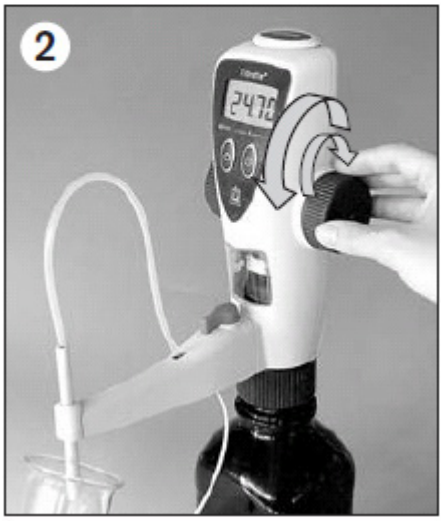
The instrument must be cleaned every 8 weeks or if any of the following should occur:

1. Must be cleaned immediately if the hand wheels become harder than usually to turn.
2. Before changing any reagent.
3. Prior to dismantling the instrument or long term storage.
4. If liquid has accumulated in the screw cap of the titration tube.

Standard Cleaning

1. Set the valve to 'Recirculation' (Fig. 1), and empty the instrument completely by turning the hand wheels.

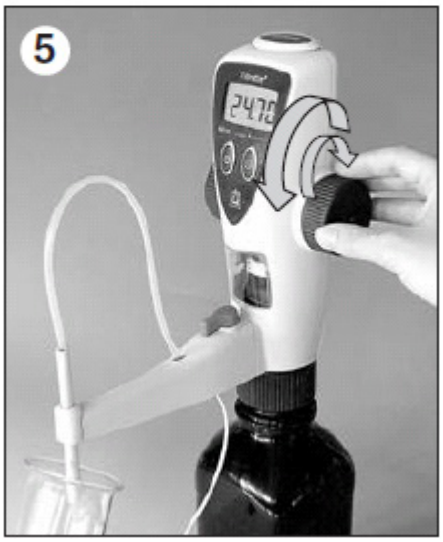
2. Screw the instrument onto a bottle filled with deionized water and rinse the instrument several times by completely filling and emptying it (Fig. 2).



3. Set the valve to 'Titrate' and unscrew the closure cap from the titration tube then place a suitable receiving vessel under the titrating tube. Rinse the instrument several times by completely filling and emptying it (Fig. 3).

4. If deposits appear in the dispensing cylinder, this process can be repeated with a suitable cleaning agent followed by another thorough with deionized water.

5. Screw the instrument onto an empty bottle and empty the piston completely by turning the fill/dispense knob back and forth in both the "Recirculation" and in the "Titration" valve setting (Fig. 5).



6. Unscrew the air vent cap by hand or use a coin.

7. Remove the rear housing and take out the mounting tool.

8. Loosen the safety ring of the piston/cylinder assembly with the mounting tool, and unscrew it completely by hand (Fig. 9).

9. Withdraw the locking mechanism of the piston rod up to the stop (Fig. 10).

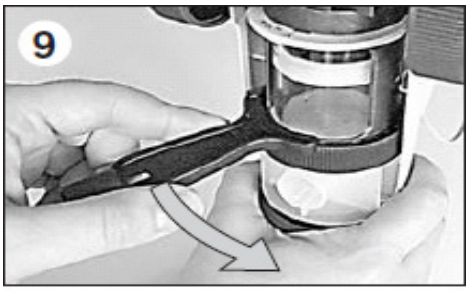
10. Move the top part of the instrument all the way to the top by turning the hand wheels, and remove it (Fig. 11).

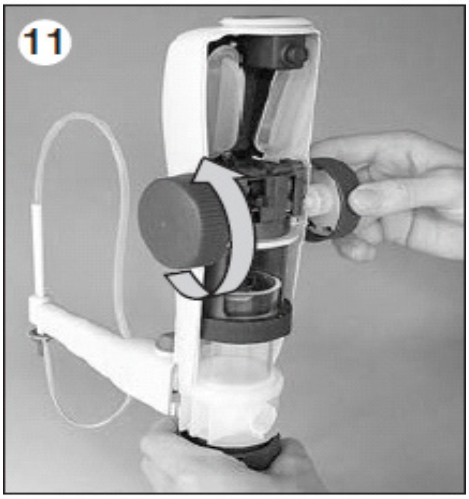
11. Remove possible crystal deposits at the upper edge of the dispensing cylinder with water and a soft bottle-brush. Then, dry it off with a lint free wipe (Fig. 12).

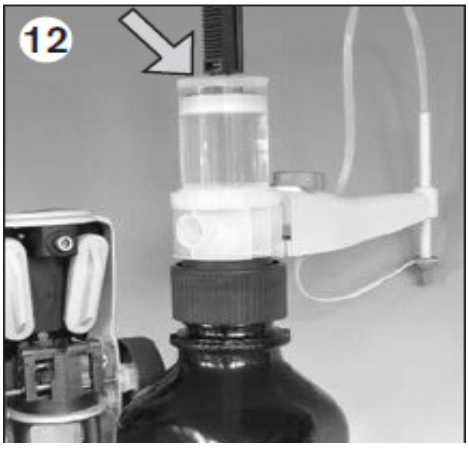
12. Remount the top of the instrument, or further dismantle the instrument for intensive cleaning if necessary.

13. Document Cleaning on *Maintenance Log (L15-FM-100-019)*

Notes: Depending on frequency of use, it is recommended that any crystalline deposits on top of the piston be removed on regular intervals of approx 8 weeks. For this, carry out steps 6-13.







7.0 Reference Documents:

Maintenance Log (L15-FM-100-019)

8.0 Change Information:

New Document