1.0 Purpose:

The purpose of this method is to establish a proper method for operation of the Compact Force Gauge CFG+ 200N used for testing the pull strength of the rare earth magnets located in the manufacturing facility. This procedure will also describe how to correctly test the pull strength of the magnets. The following will prove with documented evidence the facilities ability to stay compliant with 21 CFR sections 211.67(a) and 211.84(d)(5) as well as FDA's *Compliance Program Guidance Manual* 7356.002 "controls to prevent contamination".

2.0 Scope:

This procedure is to be performed in the manufacturing facility biannually by qualified QA personnel or designee.

3.0 Responsibility:

Qualified QA personnel or designee is to perform this procedure and the data will be reviewed by QA for completion and conformance.

4.0 Safety Considerations:

Proper PPE should be worn at all times during this procedure. Including but not limited to gloves, safety goggles, and steel toed shoes.

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:

- Compact Force Gauge CFG^{+} 200N

6.0 Procedure:

Meter Operation –

- Attach the ¼" ball attachment to the lower portion of the meter using the clip provided.
- Turn meter on using the 'POWER' button.
- Verify that the meter is reading MAX and Newton's (N) on the display. If not use the 'MAX' and 'UNITS' button as needed.
- Before taking a measurement, zero the display by pressing the 'ZERO' button.
- After use, turn the meter off by holding the 'POWER' button.

Measuring Magnet Strength –

- Allow the ¼" ball apparatus on the meter attach to the magnet.
- Slowly and carefully pull the meter by the lanyard until the ball detaches.
- Record the reading on the display into *Magnet Strength Test (Q15-PR-100-F027).*
- Repeat test on all magnets in the facility.
- If the force obtained is > 15.0N, management must be notified immediately and the magnets should be replaced.

7.0 Reference Documents:

Magnet Strength Test (Q15-PR-100-F027)

8.0 Change Information:

New Document