



## GILES CHEMICAL ~ PREMIER MAGNESIA

### Company Procedure

Title: **Production Calibration**

Number: **M13-PR-100-001**

Owner: **Brook Vaughn**

Revision: **2**

Effective Date: **5/1/2015**

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### 1.0 Purpose

The purpose of this procedure is to ensure that equipment used in the manufacture, process, packing and holding of a drug product is calibrated and inspected as outlined in 21 CFR 211.68.

### 2.0 Scope

This procedure shall be performed monthly by an approved 3<sup>rd</sup> party vendor for all scales and balances used at Giles facilities.

### 3.0 Responsibility

Maintenance - administers the scale calibration program for production.

Quality – retains calibration documents

### 4.0 Safety Considerations

Safety glasses and appropriate safety apparel is to be worn at all times.

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

#### Laboratory Scale

| Manufacturer | Model Number | Serial Number | Graduation/Capacity |
|--------------|--------------|---------------|---------------------|
| Sartorius    | B410 OUR     | 39100001      | .01 G / 400 G       |

#### Manufacturing Scales

|                |                    |             |                     |
|----------------|--------------------|-------------|---------------------|
| Metler-Toledo  | IND560 / Flexweigh | 00605676HH  | 1 lb / 3000 lb      |
| Mettler-Toledo | PTHK               | 5150018-5FB | 1 lb / 5000 lb      |
| AND            | FS-60KL            | 4500227     | .02/.05 lb / 150 lb |
| Rice Lake      | IQ-710-2A          | 1473900097  | 1 lb / 5000 lb      |
| Mettler-Toledo | IND560 Fill        | 04492096MM  | 1 lb / 5000 lb      |

#### Repackaging Scales

|                |       |                 |                  |
|----------------|-------|-----------------|------------------|
| NCI            | 3250  | SR20900295      | 0.01 lb / 15 lb  |
| Mettler-Toledo | SW15K | 5436063-5FF     | 0.01 lb / 30 lb  |
| Mettler-Toledo | SW15K | 5436062-5FF     | 0.01 lb / 30 lb  |
| Ohaus          | AR310 | 12171225210561P | 0.001 g / 310 g  |
| Toledo         | 8213  | 2679346-2PU     | 0.02 lb / 100 lb |

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|----------------|-----------------|--------------------------|-----------------|
| Mettler-Toledo | PTHK            | 0011374-6AJ              | 1 lb / 5000 lb  |
| Mettler-Toledo | SW15K           | 56307935DL               | 0.01 lb / 30 lb |
| Mettler-Toledo | 1CS449          | B610181157               | 0.01 lb / 30 lb |
| Mettler-Toledo | SW06KP          | 56391685HL               | 0.01 lb / 12 lb |
| Mettler-Toledo | SW06KP          | 56519035BM               | 0.01 lb / 12 lb |
| Ohaus          | VALOR3000XTREME | 7132030367               | .01 g / 200 g   |
| Ohaus          | VALOR3000XTREME | 7132641505               | 0.01 g / 200 g  |
| Ohaus          | VALOR3000XTREME | 7132120068               | .01 g / 200 g   |
| Ohaus          | VALOR3000XTREME | B318283250               | .01 g / 200 g   |
| Ohaus          | VALOR3000XTREME | B350095676               | .01 g / 200 g   |
| Ohaus          | VALOR3000XTREME | B205657164               | .01 g / 200 g   |
| Ohaus          | VALOR3000XTREME | 7132120102               | .01 g / 200 g   |
| Ohaus          | V31XH202        | B543604508               | .01 g / 200 g   |
| Mettler-Toledo | IND236 / 2256   | B407287407               | .1 lb / 1000 lb |
| Mettler-Toledo | BBA231          | B346982980               | .01 lb / 60 lb  |
| Mettler-Toledo | IND246          | B502457974               | .1 lb / 1000 lb |
| Mettler-Toledo | IND226 / 2256   | B227086391 / 1187861-1JP | .1 lb / 1000 lb |
| Mettler-Toledo | IND236          | B542581722               | .1 lb / 1000 lb |

## 6.0 Procedure

Scale calibrations occur once a month. Maintenance will call vendor if additional services are needed between scheduled monthly visits.

Scale certificates are issued for calibration each monthly visit.

Work orders are issued for repairs as needed.

Scale calibration documentation will be retained by the Quality Unit in the cGMP library.

## 7.0 Reference Documents

N/A

## 8.0 Change Information

Corrected the serial number of one Ohaus scale and added 3 scales to the Repackaging list.

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