
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: Production Calibration	Number: M13-PR-100-001	
	Owner: Brook Vaughn	Revision: 1	
	Effective Date: 7/20/2015	Page: 1 of 2	

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 3rd 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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Page: **2 of 2**



Mettler-Toledo	PTHK	0011374-6AJ	1 lb / 5000 lb
Mettler-Toledo	SW15K	56307935DL	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	7132041505	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
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

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

General update.

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