

Certificate

We hereby certify, that the below mentioned products meet

*GMP-guidelines, EG –GMP-Annex 15 guideline
and PIC/S guideline PI 006-3 requirements.*

Products: **SWB805 MultiMount™**
 SLB815 Load Cell
 AJB941M Junction Box
 Weigh Module Mounting Kits

Manufacturer: **Mettler-Toledo(Changzhou)**
 Precision Instrument Ltd.
 No. 22 Zhengqiang Road,
 Changzhou, Jiangsu, P.R.China

Gau-Algesheim, March 2018

Prof. Ronald Ziegler M. Sc.

Roland Pichler, *Dipl.-Ing.(FH) Pharmatechnik*

Index

1. Description of the products	3
1.1 SWB805 MultiMount™	3
1.2 SLB815 Load Cell.....	3
1.3 AJB941M Junction Box.....	4
1.4 Weigh Module Mounting Kits	5
2. General requirements for Industrial Scales.....	6
3. Appraisal criteria for an optimal cleaning	7
4. Appraisal factors for qualification.....	10

1. Description of the products

1.1 SWB805 MultiMount™

The SWB805 is a fully approved hygienic weigh module for food and pharmaceutical applications.

Model no.:	SWB805 MultiMount
Material:	304 stainless steel / 316 stainless steel HD-9570 Silicone Rubber
Finish:	Electro polish, final mirror polish, RA < 0.8µm
Hygienic approval:	NSF



1.2 SLB815 Load Cell

Load Cell for SWB805 MultiMount Weigh Module



Model no.:	SLB815
Rated capacity (R.C.) [kg (lb, nominal)]:	110 (250), 220 (500), 550 (1,250), 1100 (2,500), 2,200 (5,000), 4,400 (10,000)

Temperature range [°C (°F)]

Compensated:	-10 ~ +40 (+14 ~ +104)
Operating:	-40 ~ +65 (-40 ~ +150)
Safe storage:	-40 ~ +80 (-40 ~ +176)

Hygienic approval

Hygienic approval:	NSF
--------------------	-----

Excitation voltage [V AC/DC]

Recommended:	5 ~ 15
Max.:	15

Terminal resistance Ω

Excitation:	384 \pm 10
Output:	350 \pm 1

Material

Spring element:	17-4 PH stainless steel
Finish:	Electro polish, final mirror polish, RA < 0.8 μ m

Protection

Type:	welded
IP rating:	IP68, IP69K
NEMA rating:	NEMA 6/6P

Cable

Diameter [mm (in)]:	PVC: 5.2 (0.2)
---------------------	----------------

1.3 AJB941M Junction Box

Precision Junction Boxes are intended to connect analog load cells and allow very precise shift adjustment by selecting precision resistors via two hex-step switches.

P/N:	30219978
Size:	Medium
Application:	Hygienic
No. of load cells:	2, 3, 4



Temperature range [°C (°F)]

Operating:	-30 ~ +65 (-4 ~ +150)
Safe storage:	-40 ~ +80 (-40 ~ +176)

Material

Enclosure:	316 stainless steel, FDA approved
Cable entry fitting:	stainless steel
Finish:	Electro polish, final mirror polish, RA < 0.8µm

Protection

Type:	Silicon
IP rating:	IP69K

Hygienic approval

Hygienic approval:	NSF
--------------------	-----

1.4 Weigh Module Mounting Kits

Welding and bolting kits are available which meet hygienic requirements. These kits contain hygienic fasteners and seals for all metal to metal interfaces. The top and base plates may be secured using Welding Kits, Bolt Kits, or Concrete Kits. Any combination of kits can be used for the top and bottom mounting.

2. General requirements for Industrial Scales

Industrial Scales (weigh modules) have to show the suitable measurement range and the required precision (EC-GMP guide¹, chapter 3.40).

They have to be calibrated regularly, which has to be documented (EC-GMP guide, chapter 3.41).

The permitted tolerance must be provided for the respective weighing capacity, by consideration of the measuring inaccuracies, i.e. the still tolerated deviation of the debit value.

Working with raw materials, the equipment and the utensils used have to meet the requirements for surfaces in pharmaceutical production.

According to § 211.65 “Construction of the equipment”² of the FDA: *„(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.”*

The cleaning ability is confirmed by the cleaning validation. Established cleaning instructions are necessary as a prerequisite for a cleaning validation.

The amount of permitted residuals whether active pharmaceutical ingredients or cleaning agents, is dependent on the preliminary manufactured product. These include the derivative product and the lot size of the derivative product. A first, general statement for not critical products can be made with the criteria "visual clean". According to the literature³, backlogs of 375 µg per 100 cm² are no longer visible.

¹ EC-GMP guide, chapter 3.40

² USA 21 CFR Part 211

³ Buscalferri et.al., Pharmind 62, Nr. 6 (2000)

3. Appraisal criteria for an optimal cleaning

General

In principle, those parts of equipment, which come into contact with the product, have to be cleaned well. Regarding the balances, these parts are the load plates.

Both the FDA inspection guideline for cleaning validation and the PIC guideline PIC/S 006-3 cite the visual criterion as one out of three possible acceptance criterions. From these the most appropriate criterion has to be chosen to appraise the cleaning success.

The products SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and Weigh Module Mounting Kits were subjected to a qualified examination regarding "cleaning ability"⁴. This means that the surfaces of the products SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and Weigh Module Mounting Kits must be free of visible residuals after cleaning. As a basis for this examination the works of Buscalferri, F., Assignment of the visibility limit of pharmaceutical active agents ("Bestimmung der Sichtbarkeitsgrenze von pharmazeutischen Wirkstoffen"), master thesis, Albstadt-Sigmaringen University, course of studies pharmaceutical technology (1999) and Fourman, G. L., Mullen, Determining Cleaning Validation Acceptance Limits for Pharmaceutical Manufacturing Operations, Pharm. Technol. 17 (4), 54 (1993) were used.

⁴ The examinations and their evaluation were carried out by Prof. R. Ziegler

Procedure

A granulated material, which was coloured with Erythrosine, was used as a sample. The examinations⁵¹ were carried out according to the “visually clean” criteria (please see “GMP Berater” 8.E.1.5). First the load plates of the products SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and Weigh Module Mounting Kits were polluted, following by a cleaning step. A cleaning agent (P3-cosa PUR 80 Manufacturer: Ecolab GmbH & Co. OHG, Düsseldorf), which is commonly used in pharmaceutical production was taken and feigned according to different pollution degrees.

The cleaning success was then appraised visually.

The exact data can be taken from the test report. These results show clearly, that the depletion degree meets in principle the hygienic requirements. In principle the depletion degree is dependent on the examined material and the specific requirements of the examination.

Results

In regard to the cleaning, the products SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and the Weigh Module Mounting Kits , correspond to the visually clean criteria.

⁵ These experiments were performed by Prof. R. Ziegler

Summary

The construction of the products SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and the Weigh Module Mounting Kits are GMP-compliant. The cleaning of the parts, which come in contact with the product, has to be carried out well. There are no inaccessible places where dust can accumulate. Once the load plate is installed, the load plate will be welded to the vessel, so that the cleaning of the parts which are not in contact with the product is guaranteed.

The SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and Weigh Module Mounting Kits are easy to clean as well. Every part is easily accessible. The mechanic components are constructed according to the GMP guidelines.

4. Appraisal factors for qualification

General

The PIC/S guideline PI 006-3 and the EG-GMP guide Annex 15 mention principles for qualification and validation.

Every machine or equipment which directly or indirectly influences the quality of the product shall be qualified. The machine or equipment shall be designed in agreement with the prevailing GMP guidelines. The machine shall be installed in agreement with the design specification and the functions shall be checked with the available documentation (functional qualification).

Procedure

The available documentation of the METTLER TOLEDO products SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and Weigh Module Mounting Kits was checked to the effect of whether design qualification, installation qualification and functional qualification are feasible.

Results

The documentation of the METTLER TOLEDO products SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and the Weigh Module Mounting Kits is very detailed. Also an exact description of the modules with design drawings is available. The materials used are described precisely.

GMP-relevant documents are available (e.g. inspection certificate, CE-mark). Particulars regarding the maintenance are furnished.

Summary

The documentation of the manufacturer of the METTLER TOLEDO products SWB805 MultiMount™, SLB815 Load Cell, AJB941M Junction Box and the Weigh Module Mounting Kits is written in a very detailed way and offers the necessary conditions for the execution of qualification, as it is demanded by EG-GMP guide Annex 15 and PIC/S guideline PI 006-3.