

Standard Operating Procedure Title: Operation of Checkweigher

The Checkweigher is used to detect cartons containing under or over weight product and/or missing product, so the cartons can be rejected before further processing.

- 1. Daily Operation
 - 1.1. Powering up the Checkweigher. To ensure the Checkweigher is working correctly, perform challenge tests as detailed in Section 4.
 - 1.2. The Checkweigher is ready for production.
- 2. Product Change
 - 2.1. The Checkweigher is designed to hold in memory the different products parameters. These are predetermined and programmed into the memory during the validation process of each new product.
 - 2.2. During a changeover when the new product details are required for the next batch, follow the checkweigher manual.
- 3. Challenging the Checkweigher
 - 4.1 Run the product through the Checkweigher, and on each occasion, ensure the product is correctly rejected. This is to be performed at the start of each batch and the results recorded in the MI sheet (See SOP MAN-080). This is also to be challenged at the start of every day and the results recorded in the MI logbook.
 - a. A full carton, minus one blister
 - b. A full carton with one extra blister
 - c. If leaflets are included challenge, then check weigh with one full carton with no leaflet and then one with two leaflets.
- 4. Method of determining Product Parameters, including Upper and Lower limits
 - 4.1. Produce a schedule to add the average weight of each component required to produce the finished product and quantity of blisters. This is determined using calibrated Laboratory scales over a sample of ten products. Added together this gives the average weight of the finished product.
 - 4.2. From experimental data, it has been shown that the finished carton when measured on a top pan balance varies by ± 0.15 g. The same sample of finished cartons when passed across the Garvens Checkweigher, varied by ± 0.8 g. This difference is that the Checkweigher is measuring at speed and is affected by orientation of the product and any air movement.
 - 4.3. The allowable variation in weight measured during production needs to take into consideration the above variation of the equipment $(\pm 0.8g)$ and the minimum component weight. In most cases the minimum component weight is in the proximity of 4g hence a tight tolerance is not required. For these products a tolerance of $\pm 2.0g$ has been chosen. For products with a minimum component weight of 1.7g, (e.g. leaflet) then the tolerance is tightened to $\pm 1.0g$.
 - 4.4. The function of the Checkweigher is not to check for the quantity of tablets. The Checkweigher looks for missing components, like cartons, blisters or leaflets.

5. Changing Parameters

- 5.1. If the Checkweigher rejects product that has the correct product description entered, do the following:
 - 5.1.1. Stop the batch; investigate what has caused the variance. If the outcome of the investigation shows that the Average reference weight requires changing, re-

This is not an approved copy unless stamped in red