SARTORIUS

Application Highlight

According to European pharmacopoeia to ensure the consistency of dosage units tablets and capsules containing 25 mg or more of an active substance(s) must be checked. The uniformity of the amount of active substance(s) in a given number of units single-dose medications is important to prevent under or over dosage.

Tablet Check
Check of Tablets and Capsules

Different standardized tests must be conducted to measure the content of active substance(s), uniformity of content, disintegration time, dissolution and uniformity of weight. These tests are used to determine the content and the in vitro release of the active substances(s). The test for the uniformity of weight is performed by weighing individually tablets or capsules randomly selected from a batch and determining their individual weight | filling weight.

Cubis® II MCA balances with tablet feeder and QApp tablet check offer a convenient solution to investigate tablets and capsules according to Pharmacopoeia (Image 1). Users with the role to create tasks are allowed to create new products and to set product parameters. For the product to be tested the product type (tablet or capsule) nominal weight, minimum lower and upper tolerance, maximum lower and upper tolerance and plausibility must be defined (Fig. 1). Additionally the calculation mode can be set. For the results calculation the dynamic tolerance can be switched on or off.

If inactivated the results are calculated by using fixed tolerances. With the dynamic tolerance switched on permissible limits are calculated either based on the mean value and are recalculated after each sample measurement or based on the average mean value after measuring all samples. Furthermore a plausibility value is set to identify measured sample weights out of a plausible range. Out of plausibility samples are excluded from the results calculation.

During the test procedure the number of samples is set by the user. If tablets are measured the samples are placed one after another on the balance either manually by the user or automatically by a connected tablet feeder until the specified number of samples is measured. For capsules first the average mean weight value of empty capsules is determined or entered by the user.

Then filled capsules are measured one after another to determine the filling weight by subtracting the average mean weight value of the empty capsules from the measured weight of each filled capsule. Also weighing of capsules can be automated connecting a tablet feeder.

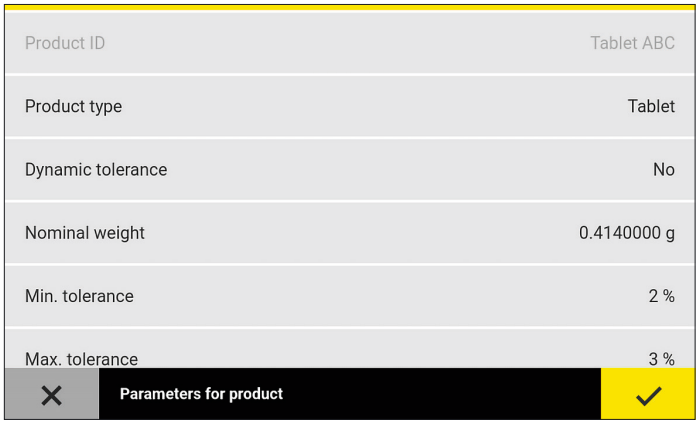

Figure 1: Tablet check product parameter settings

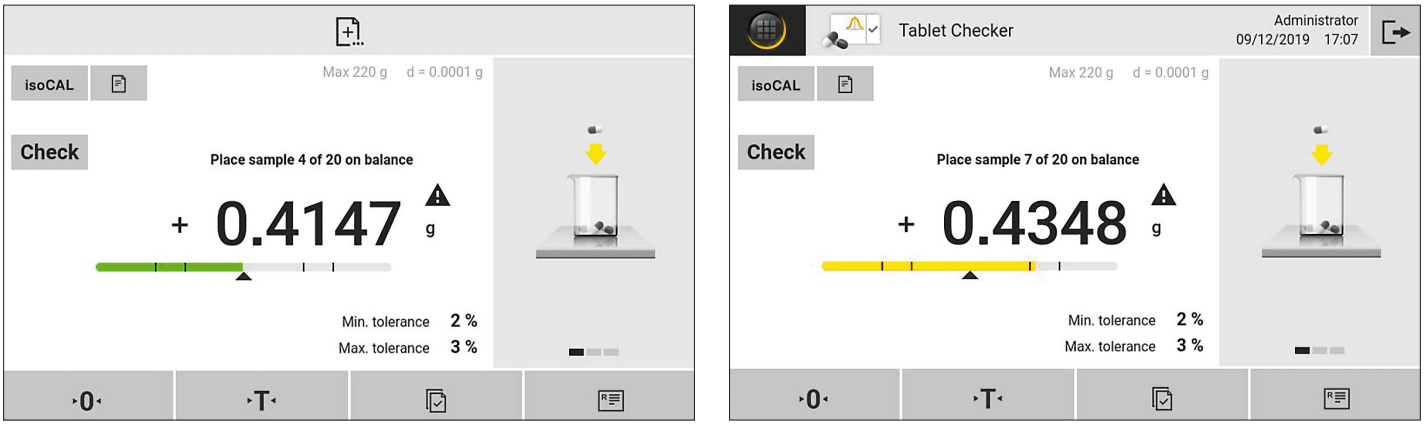

Figure 2: The tolerance bar color indicates if the measured sample weight is within the permissible tolerances. Green = Sample weight within minimum tolerance, yellow = sample weight between minimum and maximum tolerance, red = sample weight above maximum tolerance

If the results are evaluated using fixed tolerances or dynamic tolerances with recalculation after each sample a tolerance bar is displayed. If the measured sample weight is within the set lower and upper minimum permissible limit the tolerance bar is shown in green, if the weight is between the minimum and maximum tolerance the tolerance bar color switches yellow and for samples weights out of both limits the tolerance bar is shown in red. By this color code the operator gets a visual feedback during the measurement for each single sample.

After the specified number of tablets is measured the software creates and displays a summarizing statistics. Displayed are the mean, minimum and maximum measured tablet or filling weight value, standard deviation, total count and number of tested samples that passed the test, are out of minimum tolerance, out of maximum tolerance or out of plausibility (Fig. 3). The software can also create a cumulative statistics to summarize the result of multiple lot measurements and calculates the number of sample that passed the test or are out of minimum tolerance, out of maximum tolerance or out of plausibility.

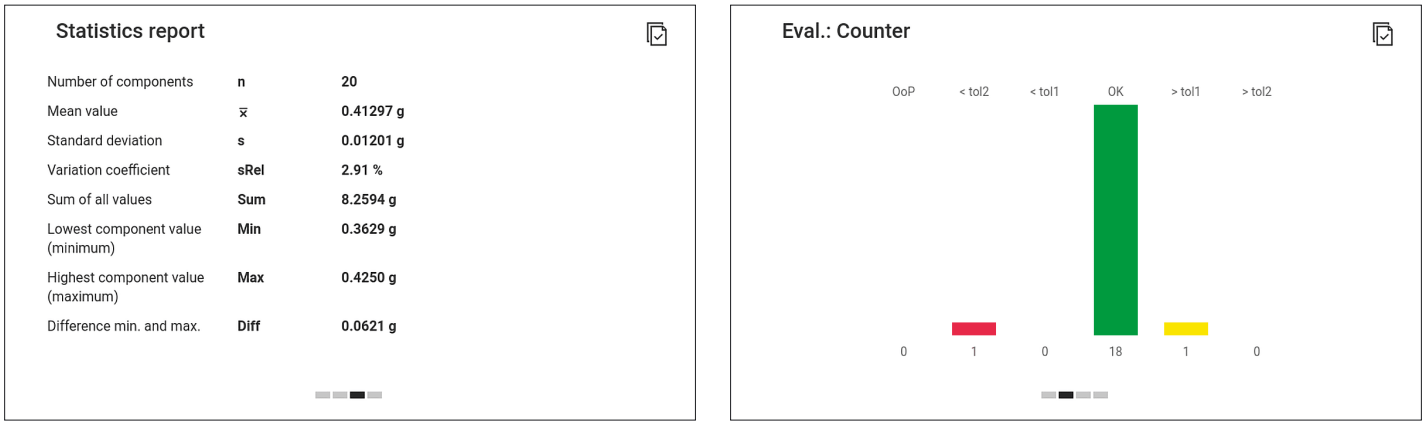

Figure 3: Tablet check statistics report (left) and summarizing bar chart (right)

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