

PHARMA SOLID KNOWLEDGE REPORT

Reliable empty capsules inspection.

TARGET

Are Syntegon KKE checkweighers well usable for empty capsule checkweighing? Is special machine equipment required?

Background: More demanding weight quality requirements in the production and use of empty capsules.

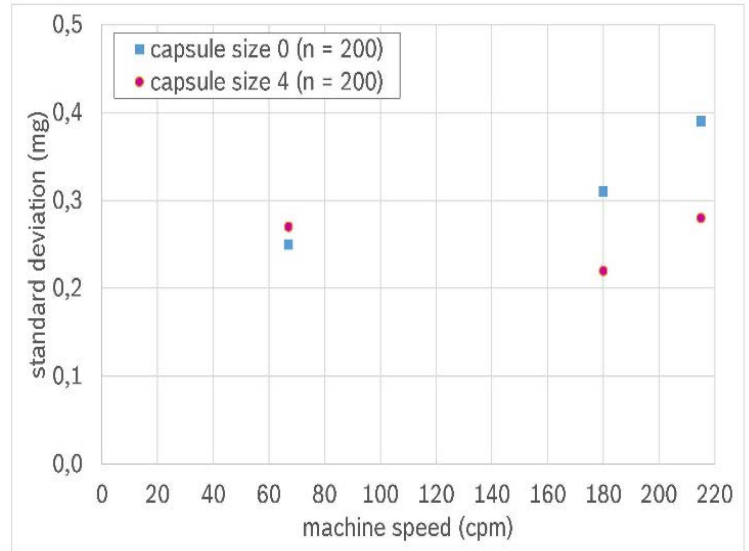
TEST

A KKE 3800 in basic execution (with 2 mg weighing cell and no separate weighing base) was investigated regarding accuracy, repeatability, process stability and productivity.

ACCURACY

The KKE 3800 was set to acceptance intervals of 0.4 mg (+/- 0.2mg) for gelatin capsules, for sizes 0 and 4. The KKE was operated at machine speeds of 67, 180 and 215 cycles per minute. 200 capsules from each trial run were weighed using an analytical balance (XPE205, Mettler Toledo).

The average deviation between KKE and the analytical balance is due to small changes in capsule moisture content.



Comparison of KKE 3800 and lab scale results

		Capsule size 0 (gelatin)			Capsule size 4 (gelatin)		
KKE	Machine speed (cycles per minute)	67	180	215	67	180	215
	Mean value (mg)	95.0*	95.0*	95.0*	38.0*	38.0*	38.0*
	Mean value (mg)	94.60	95.00	94.78	38.01	38.22	38.24
analytical balance	Standard deviation (mg)	0.25	0.31	0.39	0.15	0.18	0.25
	3σ (mg)	0.75	0.93	1.17	0.45	0.54	0.75
	Variation coefficient (%)	0.27	0.32	0.41	0.39	0.46	0.66
	Min. weight (mg)	93.95	94.14	93.47	37.51	37.72	37.56
	Max. weight (mg)	95.33	95.80	95.70	38.44	38.70	38.95
	Weight range (mg)	1.39	1.66	2.23	0.93	0.98	1.39



KKE Series – the ideal partner for high-precision capsule checkweighing

Our focus is on your product. Our solutions for your quality inspection needs.

REPEATABILITY

30 empty gelatin capsules, sizes 0 and 4, were identified with numbers from 1 to 30. Each capsule was weighed three times via the KKE 3800 at machine speeds of 67, 180 and 215 cycles per minute.

Repeatability results for capsule size 0 and KKE speed 180 cycles per minute

Capsule No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Mean value (mg)	91.0	91.4	91.0	92.6	88.8	90.4	91.1	93.1	92.9	92.7	93.3	91.9	91.7	93.6	91.7
Standard deviation (mg)	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.1
Variation coefficient (%)	0.13	0.22	0.22	0.22	0.23	0.22	0.25	0.12	0.12	0.12	0.12	0.13	0.13	0.00	0.13
Min. weight (mg)	91.0	91.2	90.8	92.4	88.6	90.2	91.0	93.0	92.8	92.6	93.2	91.8	91.6	93.6	91.6
Max. weight (mg)	91.2	91.6	91.2	92.8	89.0	90.6	91.4	93.2	93.0	92.8	93.4	92.0	91.8	93.6	91.8
Weight range (mg)	0.2	0.4	0.4	0.4	0.4	0.4	0.4	0.2	0.2	0.2	0.2	0.2	0.2	0.0	0.2
Capsule No.	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Mean value (mg)	90.0	94.1	94.5	90.6	94.3	91.1	92.6	89.9	93.5	92.2	89.8	93.6	91.3	93.6	89.7
Standard deviation (mg)	0.0	0.1	0.1	0.0	0.1	0.1	0.0	0.1	0.1	0.2	0.2	0.0	0.1	0.0	0.1
Variation coefficient (%)	0.00	0.12	0.12	0.00	0.12	0.13	0.00	0.13	0.12	0.22	0.22	0.00	0.13	0.00	0.13
Min. weight (mg)	90.0	94.0	94.4	90.6	94.2	91.0	92.6	89.8	93.4	92.0	89.6	93.6	91.2	93.6	89.6
Max. weight (mg)	90.0	94.2	94.6	90.6	94.4	91.2	92.6	90.0	93.6	92.4	90.0	93.6	91.4	93.6	89.8
Weight range (mg)	0.0	0.2	0.2	0.0	0.2	0.2	0.0	0.2	0.2	0.4	0.4	0.0	0.2	0.0	0.2

Conclusion

- The Syntegon KKE checkweighers are ideally suited to handle empty gelatin as well as HPMC capsules. The integrated cGMP and ASB technology (automatic trouble-shooting) guarantee extremely high productivity and overall equipment effectiveness (OEE). The permanent positive mechanical guidance of the capsules guarantees maximum pharmaceutical security. In addition, the Syntegon KKE series stands for high production uptimes and the comprehensive documentation of its production batches (batch report).
- The precise gravimetric weighing technology, as well as simple handling and size changeover, make the KKE series the ideal choice for your 100% empty capsule checkweighing needs.
- Special features for handling empty capsules in an ideal manner: The tendency of empty capsules to become electrostatically charged can be solved easily by the implementation of an ionizing bar. Special aerodynamic transport fingers also improve the weighing process stability by reducing air currents.
- The results for accuracy and repeatability prove a very low standard deviation for the KKE series with the standard 2 mg weighing cell.
- The optimum KKE 3800 speed for checkweighing empty capsules is 180 to 185 cycles/minute, which equals appr. 85% of the nominal max. speed.
- No difference was observed between the capsule sizes investigated (gelatin capsule size 0 and 4).
- Note: As empty capsules are sensitive to changes in environmental conditions, the moisture equilibration is of particular importance for empty capsule check weighing.

More Questions?

You also have processes for optimization?

Please contact us. Our "Engineering Pharmaceutical Service" team will be available with all our experience of over 50 years:

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