

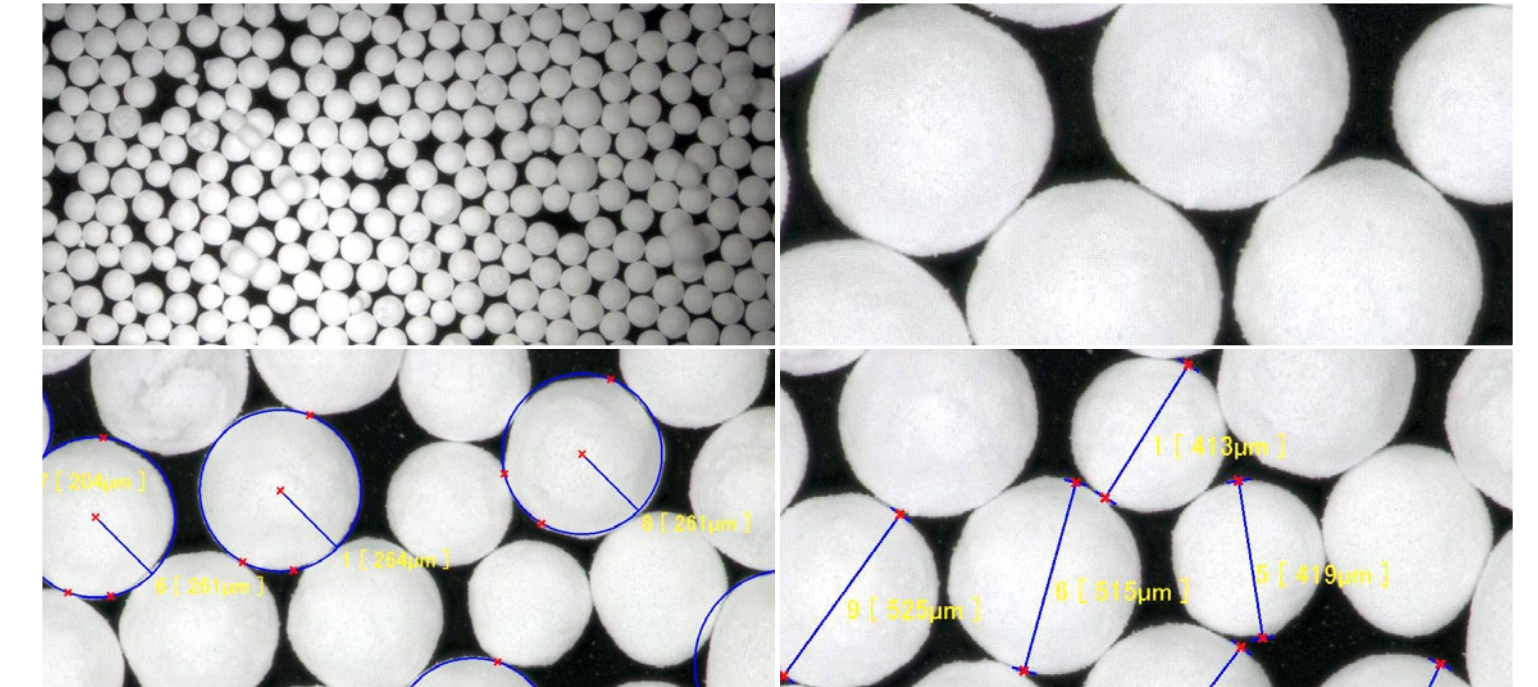
Target

A new trend in manufacturing technology is the production of lyophilized pellets in bulk instead of lyophilization of cakes within vials. These lyophilized pellets need to be dosed individually into containers, such as diagnostic cartridges or similar.

Material and equipment

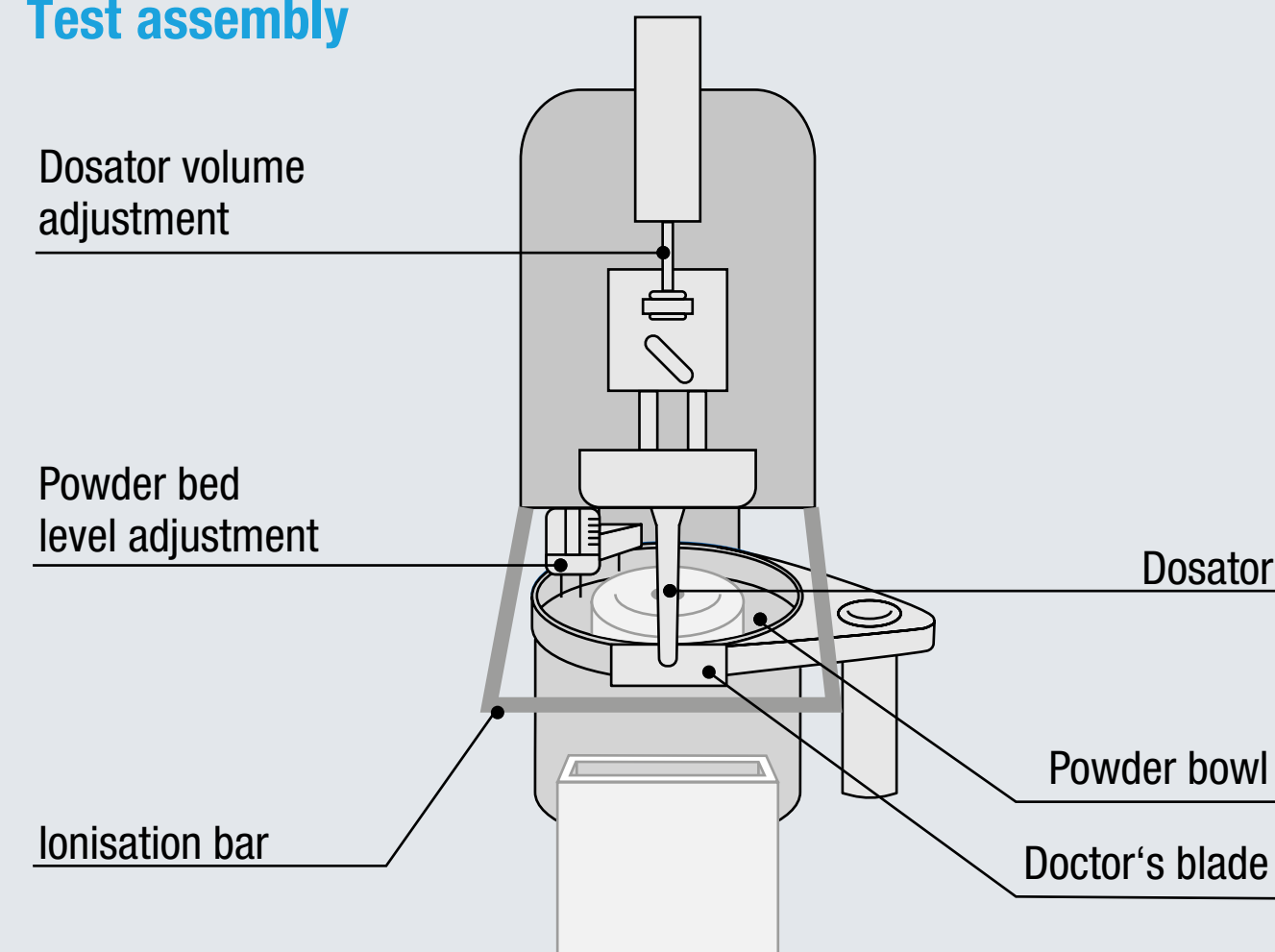
The vacuum dosator doses lyophilized pellets by volumetric means. The vacuum dosator sleeve moves into the “powder bed” and sucks material into its dosing volume. The vacuum is kept while the dosator moves over the container to be filled. The material is transferred into the container by an air impulse.

Visual impression of lyophilized pellets

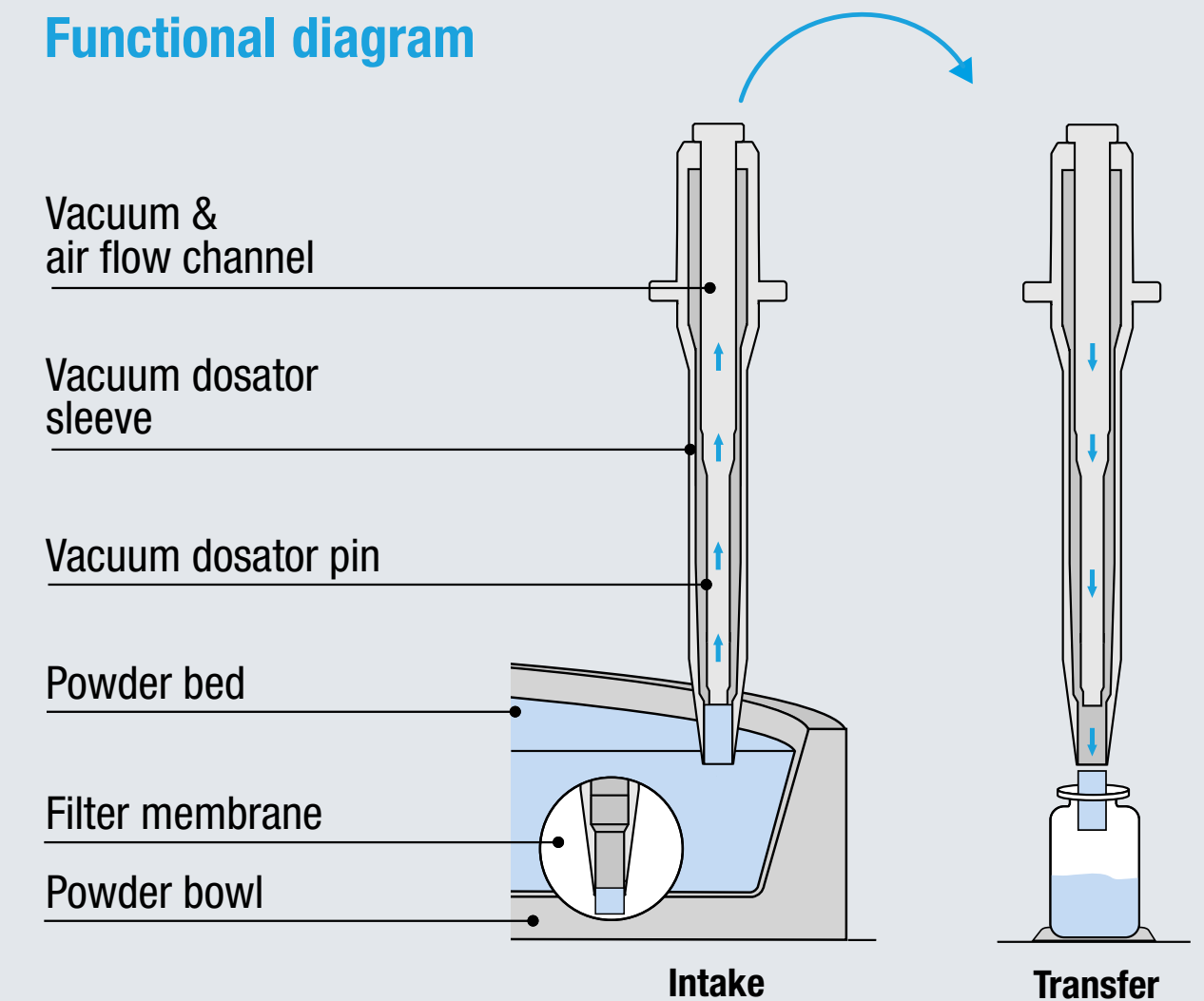


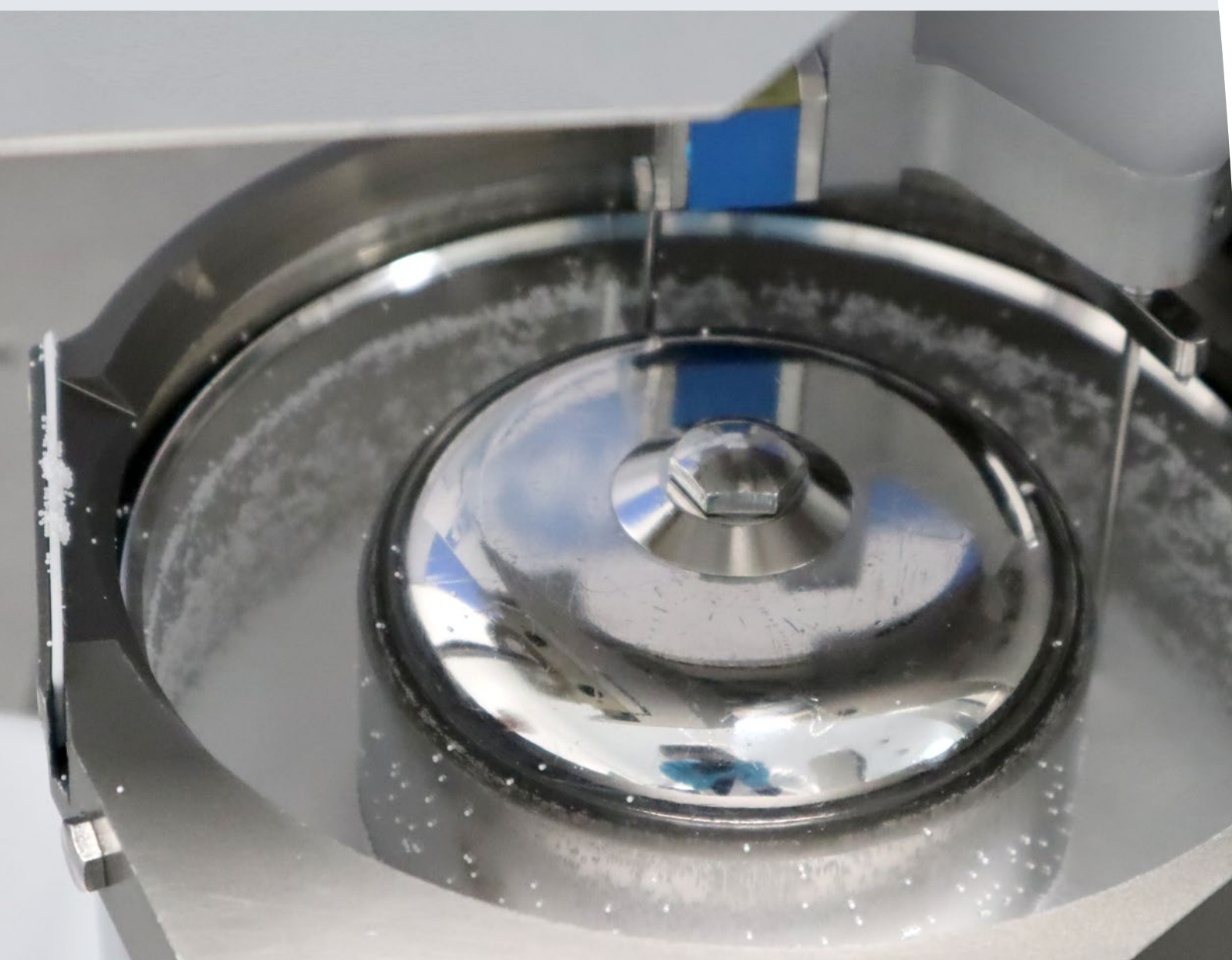
- + Sensitive dosing technology with low shear forces
- + Broad range of dosing weights
- + Inline adaption of dosing weight
- + Upscaling very easy by multiplication of vacuum dosator sleeves

Test assembly



Functional diagram





High electrostatic charge of pellets may typically lead to buildup on machine parts. For proper dosing it is therefore necessary to find counter measures.



A member of
Excellence United

Harro Höfliger Verpackungsmaschinen GmbH · www.hoeffliger.com

Electrostatic charge is a challenge during dosing of lyophilized beads

As they are sensitive to humidity due to the production technology of lyophilization, they need to be processed at low humidity conditions.

In contrast to this need, electrostatic behaviour increases with decreasing rh environmental conditions. For proper dosing, it is therefore necessary to find the right balance or counter measures against electrostatic charge.

Summary and conclusion

■ Product characterization

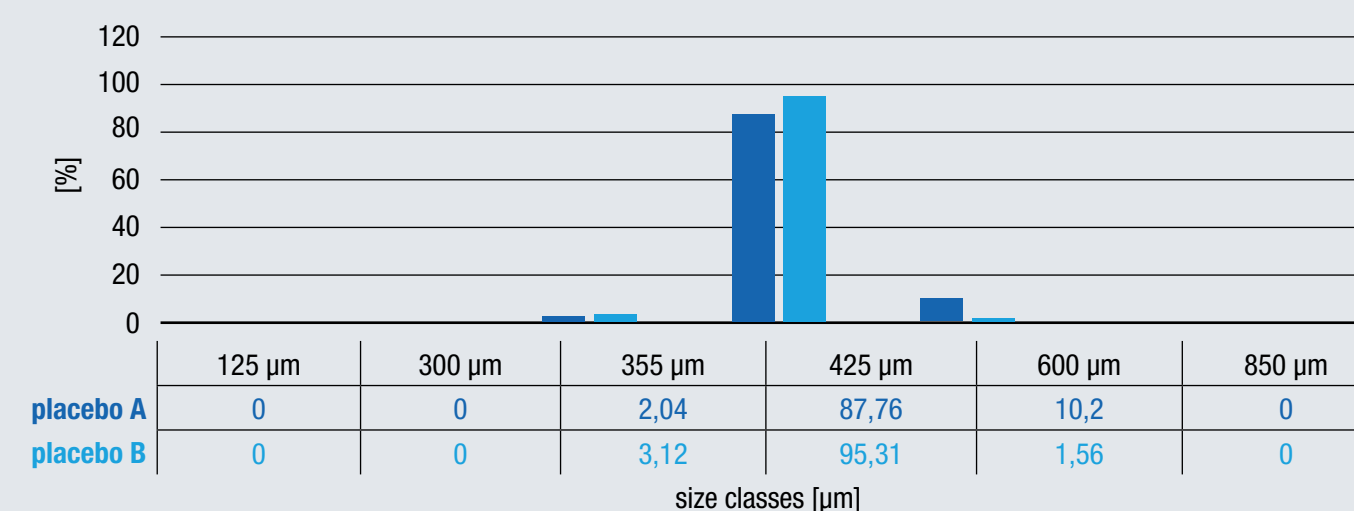
The lyophilized pellets are very homogenous in geometry (spherical) and have a narrow particle size distribution. The flowability is good. There is some electrostatic behaviour. The mechanical stability is good.

■ Filling technology: Vacuum dosator

Generally, filling is feasible using the vacuum dosator. The mechanical shear forces are low, additionally the pellets are much more robust than expected. The precision and repeatability is high which was proven with a low RSD of filling. With low amount of activities any dosing weight can be filled, using different format parts (if necessary) or by adjusting the pin height for smaller filling weight changes. The dosing principle fits very well with the product.

Results of product characterization

Histogram particle size distribution by sieving tower



Results of dosing

Performance of feasibility tests using lyophilized beads (placebo A)

Position Pin [mm]	4,35	4,35	4,35	12,05	12,05	12,05
Vacuum [mbar]	-400	-400	-400	-400	-400	-400
Ejection Pressure [mbar]	500	500	500	500	500	500
Duration of Dosing [ms]	50	50	50	50	50	50
Machinery Speed [cycles/min]	20	20	60	20	20	60
Pellet Bed Height [mm]	10	10	10	10	10	10
Vacuum Dosator Size	3	3	3	3	3	3
Dosing Container	alu container	glass vial	alu container	alu container	glass vial	alu container
Mean Weight [mg]	10,8	10,09	10,12	27,41	27,14	27,71
Min [mg]	9,92	9,86	9,91	27,24	26,69	27,60
Max [mg]	10,28	10,31	10,35	27,64	27,49	27,91
Sd [mg]	0,09	0,12	0,10	0,11	0,28	0,10
Rsd [%]	0,92	1,19	0,94	0,39	1,02	0,36
Number of Dosages	30	10	100	30	10	30