

LYOPHILISED BEADS

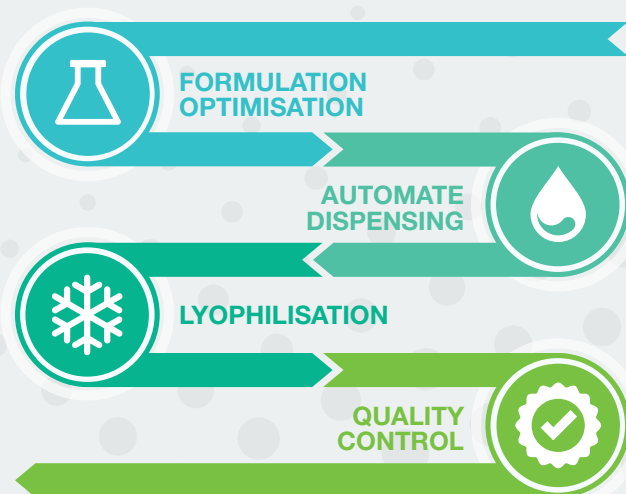
PRECISION AND CONSISTENCY AT SCALE

Lyophilising your reagents as a robust sphere containing a precise and consistent dose presents benefits in terms of assay accuracy, manufacturing efficiency, transportation and storage.

The purpose of this application note is to evidence the precision and scale of our manufacturing process by presenting data from a large-scale capability study.

OBJECTIVES

The aim of this study was to demonstrate that our lyo bead manufacturing process can deliver beads at batch sizes of at least 200,000 that meet or exceed stringent quality specifications.



METHOD

Dispensing pump pressure settings, valve actuation time, bead sink rate and dispensing cycle speed were optimised for the formulation in use.

Following optimisation, we manufactured 400,000 beads in equal-sized batches of 200,000 beads at both 10µl and 20µl dispense volumes.

The formulations were coloured with dyes to maintain pump traceability and the bead volumes were measured gravimetrically throughout the dispensing process. Bead traceability was maintained (first and last dispense) for positioning in the freeze-dryer and beads were quality assessed post-lyophilisation for size, appearance and defects.



RESULTS

For each batch of 200,000 beads, we can demonstrate the following capability of our lyo bead manufacturing process.

Measurements from start, middle and end for both 200,000 bead dispense runs, show no statistical difference across the runs.

Accuracy, precision and consistency of bead dispense at 10µl and 20µl volumes (n=400 for both 10µl and 20µl dispense volumes)

Bead Metric	Dispense Volume	
	10µl	20µl
Mean Volume (µl)	10.13	19.90
Accuracy (%)	98.7%	99.5%
Precision (CV%)	2.04%	0.78%
Lyo Bead Yield	99.6%	99.5%



CONCLUSION

The study shows that we provide an exceptionally precise, consistent, large-scale lyophilised bead manufacturing service.

We have evidenced manufacturing capability of 200,000 beads at 10µl and 200,000 beads at 20µl with a co-efficient of variance (CV) of 2.04% and 0.78% respectively.

Across the 400,000 beads, manufacturing efficiency, measured by yield, was >99.5%.

OUR OFFER

Whilst this study presents data from batches of 200,000 beads, we have the capacity to manufacture up to 300,000 beads per day.

Manufacturing is conducted in our 2,000 ft² ISO 7 (Class 10,000) humidity-controlled clean room, capable of operating consistently down to 2% RH. The clean room suite also houses five commercial scale freeze dryers and all ancillary equipment.

These facilities form part of our flexible and transparent ISO 13485 accredited contract development and manufacturing offer, which is available as a series of standalone support services or full turnkey solution designed to take your assay from conception to commercialisation.



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