

Capsule Packing Statistics Procedure

Compounders are frequently asked to formulate a capsule dosage form using a manufactured tablet or capsule as the starting active pharmaceutical ingredient (API) source or a bulk API with unknown capsule packing statistics. In order to develop a proper capsule formulation the capsule packing statistics for any unknown ingredients must first be determined. Capsule packing statistics should also be determined when receiving new lots of chemical from a chemical vendor. This is suggested for each new lot number as variances do occur from lot to lot even from the same supplier.

Capsule packing statistics for a powder, whether from crushed tablets, capsule contents, bulk API's or excipients can be determined by hand packing empty capsules. Letco recommends using a #1 capsule for the process as the results can be extrapolated to determine capsule packing statistics for other size capsules.

Hand Pack Procedure	
1	Determine average empty weight of capsule (top and bottom). Weigh 10 empty capsules then divide the total weight by 10.
2	Prepare powder by placing a sufficient amount in to a medium size weigh boat. Use a spatula to compress powder to approximately ¼ inch in height. (If material is crystalline or granular form, reduce particle size in a mortar before packing)
3	Firmly press capsule bottom into powder with a twisting motion. Repeat until capsule is completely full.
4	Recap capsule and repeat the process until 5 packed capsules are obtained.
5	Weigh each capsule and record weights.
6	Subtract average empty capsule weight from each recorded weight in Step #5.
7	Determine average weight (Sum of 5 weights/ 5)

To extrapolate the #1 capsule packing statistic to a different size capsule, multiply the #1 capsule packing statistics by the appropriate factor indicated in the table below.

Capsule Size	#5	#4	#3	#2	#1	#0	#00	#000
Factor	0.27	0.43	0.61	0.74	-----	1.37	1.95	2.95
Factor calculations are based on known capsule physical volume with slight adjustments to account for differences in packing from person to person. Results are approximations that may vary slightly from the true statistic due to a variety of factors.								