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Bella Corp. Pty Ltd

Capsule Formulation Procedure

Capsule formulations are developed by using capsule packing statistics to determine the amount of excipient required to fill a capsule in relation to the required amount of active pharmaceutical ingredient (API) required per capsule. Capsules should be calculated to be completely full. This allows for an accurate filling process when using a capsule machine and provides a pharmaceutically elegant finished dosage form. Capsule packing statistics should be determined before formulation development.

	Formulation Procedure	Example
1	Based on API dose per capsule, use capsule statistics to determine which capsule size will contain the need amount of API. (If formulating a Slow Release formulation the API should not fill more than 60% of the capsule volume if using Hypromellose 2910 (Methocel E4M) or 70% of the capsule volume if using Hypromellose 2208 (Methocel K100) slow release agents).	Rx: Progesterone 50mg Slow Release Capsule (#1 capsule) Chemical packing stats in #1 capsule: Progesterone Micronized = 0.280 g Hypromellose 2910 = 0.300 g Microcrystalline Cellulose = 0.260 g
2	Determine API capsule fill % by dividing required capsule strength by capsule packing statistic for selected capsule size. Multiply result by 100 to convert to %.	0.05 g / 0.28g = 0.179 0.179 x 100 = 17.9%
3	Subtract % result from 100% to determine remaining capsule space to be filled with excipient. Repeat Step #2 for each API in formulation and slow release agent subtracting all % results. (Slow release formulations use a standard amount of chemical: 40% capsule volume for Hypromellose 2910 (Methocel E4M) or 30% capsule volume for Hypromellose 2208 (Methocel K100).	100% - 17.9% = 82.1% 82.1% - 40% = 42.1% Progesterone Micronized = 17.9% Hypromellose 2910 = 40% Microcrystalline Cellulose = 42.1%
4	Multiply excipient's capsule packing statistic by % determined in Step #3.	Hypromellose 2910 0.300 g x 40% = 0.120 g Microcrystalline Cellulose 0.260 g x 42.1% = 0.109 g
5	Compile formulation (per capsule in grams (g)).	Progesterone Micronized = 0.050 g Hypromellose 2910 = 0.120 g Microcrystalline Cellulose = 0.109 g
6	Multiply all results by 100 to determine formulation for 100 capsules.	Progesterone Micronized = 5 g Hypromellose 2910 = 12 g Microcrystalline Cellulose = 10.9 g