

**Guidance Number: 033**

**Table 1: Matrixing of blend ratios**

Table 1			
Ratio of Amlodipine \ Statin	Strength (dosage) Amlodipine (mg) \ Statin (mg)	Amlodipine (%)	Statin (%)
1:1	10/10	13.27	10.38
1:2	5/10, 10/20	6.64	10.38
1:4	5/20, 10/40	3.32	10.38
1:8	5/40	1.66	10.38

- A. Propose a matrixing strategy of both the blend formulations and dosage strengths to use for validating the processes.
- B. What factors might affect the matrixing strategy?
- C. What should be done to validate the process to use two compressing machines that are different models? What if they are the same model and design?
- D. The source of a critical material used in the formulation, magnesium stearate, is being changed. Describe considerations for validating this change that considers the bracketing strategy used for validating the process.

**Table 2: Bracketing and Matrixing for a DP packaging process**

Table 2			
Dosage	Capsule size	Capsule fill weight	30-count bottle
120 mg	2	80 mg	80 cc
180 mg	2	120 mg	80 cc
240 mg	0	160 mg	90 cc
360 mg	0	240 mg	90 cc
420 mg	00	280 mg	120cc

Define a bracketing and matrixing strategy for the process and packaging validation that defines which dosages and how many of each should be included in the validation study.