

## SAMPLE SIZE REQUIRED FOR ANALYSIS

### POTENCY (ONLY)

- Animal Treats ..... Minimum sample – 5
- Capsules ..... Minimum sample – 5
- Creams/Lotions/Gels ..... Minimum sample – 3 mL
- Liquids ..... Minimum sample – 2 mL
- Lollipops ..... Minimum sample – 2
- Pellets ..... Minimum sample – 5
- Powder Aliquots ..... Minimum sample – 1 gm
- Suppositories ..... Minimum sample – 5
- Suspensions ..... Minimum sample – 5 mL
- Tablets ..... Minimum sample – 5
- Troches ..... Minimum sample – 5

### MICROBIOLOGICAL

**Bacterial Endotoxins** Minimum sample – 2 mL  
(only)

### STERILITY

*General Comment:*

USP <71> and proper quality control procedures dictate the number of articles and amount of product necessary for a statistically valid sterility test procedure. In general, **the more product furnished for analysis the higher the probability of detecting a non-sterile item.** The following requirements are indicative of the sample size needed to perform an analysis, not the amount that would satisfy a statistically valid sampling procedure. **If possible, a sample size sufficiently large to represent the sample, packaged in the final delivery container, allows for the best chance in obtaining a valid sterility test.**

**Sterility Test –  
Membrane Filtration**  
(only)

Minimum sample – 2 mL  
(see above)

**Rapid ScanRDI®  
Microbial Detection**  
(only)

Minimum sample – 2 mL  
(see above)

### COMBINATION TESTS

(See general comments above for sterility testing.)

**Separate samples are required for microbiological  
and potency tests.**