



International Pharmaceutical Excipients Council Of The Americas

Recommendations for Responding to Requests from USP for Samples

USP utilizes material submitted by sponsors for many purposes including development of reference standards, test methods, and compendial requirements and for evaluation of specific material attributes. USP will sometimes request excipient manufactures (i.e. sponsors) to provide samples for these purposes.

If USP requests samples from your company, you should inquire how USP intends to utilize the material to ensure that the samples you provide are appropriate.

It is not recommended to utilize automated sample request systems for providing samples to USP. Samples provided to USP should be hand selected based on how USP will use the samples, and quality personnel should typically be consulted.

If the excipient is part of a product family, you should consider how many samples of different types/grades the USP should be provided. Based on the intended purpose, you should also consider whether the samples provided should represent average batches, typical variation, or even the potential extremes of material attributes.

You should also inquire whether USP is working to develop/improve compendial test methods for the excipient and consider providing USP with in-house test methods (which may be preferable to the compendial methods).

If USP asks for information that appears unrelated (e.g. corporate contact information) or for proprietary information, follow your company's confidentiality policies.

IPEC-Americas recommends that the questions below are posed to USP whenever samples are requested:

1. Why is USP requesting these samples? How will USP use the samples?
2. If the samples will be used for round-robin testing and/or evaluation of specific material attributes, please provide the testing protocol for the study. Will the results of the study be shared with my company?
3. [If the excipient is from a product family] How many different types/grades does USP need?
4. Should the samples represent average batches with near target attributes? Or should the samples represent the full range of potential variability or extremes? Should historical ranges be considered?
5. Are there any particular parameters or attributes that should be considered when selecting sample lots?
6. How many sample lots are needed?
7. Is a CoA required?
8. Is USP seeking to partner with my company to develop any test methods?