Guideline for Donors of USP Reference Standard Candidate Materials

USP's Reference Standard program relies on the generosity of donors, who, as experts in the field, provide high-quality candidate materials intended for use as official public standards. This guidance document describes the general USP requirements for such materials. (In addition to this, USP specifications for a particular material are provided to potential donors at appropriate times.)

1. **Purity-** The minimum purity is dependent upon intended or official uses. Default purity values are listed below, but in special cases, lower-purity materials may be acceptable.

   If used in USP Assay tests (e.g., USP Acetaminophen RS): ≥ 99.5%
   If used in USP Limit tests (e.g., USP Captopril Disulfide RS): ≥ 98.0%
   If used in non-quantitative applications: case-by-case

2. **Amount-** USP accepts candidate materials in various presentations, most frequently in bulk containers or pre-packaged units (e.g., sealed ampuls). For a first-time reference standard, a minimum quantity is established in consideration of the uses of the reference material, its properties (e.g., hygroscopicity and stability), and the anticipated market demand for it. In the absence of complete information, default quantities are requested. Examples of such default values are 200 g for an active pharmaceutical ingredient or food ingredient, 1000 g for an excipient, and 50 g for an impurity.

   USP can work with smaller quantities. Donors are encouraged to discuss individual cases with USP to reach a mutually-acceptable quantity for first time materials.

3. **Supporting information**- USP recognizes that the donated material is precious to the donor and to USP. To maintain the integrity of the material, and to ensure its efficient development into an official USP standard, USP requests that the shipment is accompanied by a Certificate of Analysis (C of A), a Material Safety Data Sheet (MSDS), and a completed copy of the attached questionnaire.

   Ideally, the C of A includes all pertinent test results and the methods used to generate the results. Inclusion of IR and/or NMR spectra in the donated package, as well as stability data, when applicable, assists USP.

   The questionnaire provides USP scientific staff with additional information needed to maintain the high quality of the donated material during evaluation, packaging, and storage, including special precautions necessary for proper handling. USP experience is that timely receipt of this information saves subsequent USP and donor resources and facilitates the development of the public standards.

   A Certificate of Origin, a statement on BSE-TSE, and/or Hazardous Material status are sometimes required by national regulations.

4. **Post-donation activities-** Upon receipt of a donated bulk, USP sends an acknowledgement letter to the donor and commences the development process, which includes a multi-laboratory evaluation of the material. At the conclusion of the evaluation, USP compiles a summary data package, subdivides and labels the material, and ultimately releases the batch as a new lot of USP Reference Standard. A copy of the summary data package is sent with an acknowledgement letter to the donor.

REFERENCE MATERIAL INFORMATION	
REFERENCE STANDARD CANDIDATE NAME:	
Supplier:	Supplier Lot # :
Date sent to USP:	
Contact: Name: Phone Number: e-mail:	
1 Basis of Purity or Value Assignment	
☐	*Official USP/NF Method* (USP/NF __, page_____)
☐	*In-House Assay Method*
	☐ Reference Standard used:_
	☐ Number of assay replicates:_
	Comments:
☐	*Mass Balance Method* (% purity = 100 - % impurities as specified below)
	☐ Loss On Drying or Water
	☐ HPLC Impurities
	☐ Residue On Ignition
	☐ Additional Impurities:
2 Storage conditions	
☐	Room temperature
☐	Cool Room (between 8° and 15° C)
☐	Refrigerator (between 2° and 8° C)
☐	Freezer (between -25° and -10° C)
☐	Other_____
3 Directions for use	
☐	Dry before use Temperature: __°C time: __hrs vacuum:_____ mm Hg:____ desiccant:_____
☐	Do not dry, correct for volatiles (___LOD) or correct for moisture (___KF)
☐	Do not dry, use as-is
4 Sample preparation recommendations	
☐	Use immediately (solutions are unstable)
☐	Protect from light
☐	Refrigerate
☐	Other_____
5 Material information	
☐	Material is stable under stated storage conditions for _____ years
☐	Material is hygroscopic
☐	Material is air sensitive
☐	Material is light sensitive
6 Packaging recommendations	
☐	Ambient temperature and humidity conditions
☐	Rooms with a reduced relative humidity
☐	Inert gas-filled glove box
☐	Package under low actinic light