



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): $\geq 99.5\%$

If used in USP Limit tests (e.g., USP Captopril Disulfide RS): $\geq 98.0\%$

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	
<input type="checkbox"/>	Official USP/NF Method (USP/NF ____, page _____)
<input type="checkbox"/>	In-House Assay Method
<input type="checkbox"/>	Reference Standard used: __
<input type="checkbox"/>	Number of assay replicates: __
Comments:	
<input type="checkbox"/>	Mass Balance Method (% purity = 100 - % impurities as specified below)
<input type="checkbox"/>	Loss On Drying or Water
<input type="checkbox"/>	HPLC Impurities
<input type="checkbox"/>	Residue On Ignition
<input type="checkbox"/>	Additional Impurities:
2 Storage conditions	
<input type="checkbox"/>	Room temperature
<input type="checkbox"/>	Cool Room (between 8° and 15° C)
<input type="checkbox"/>	Refrigerator (between 2° and 8° C)
<input type="checkbox"/>	Freezer (between -25° and -10° C)
<input type="checkbox"/>	Other _____
3 Directions for use	
<input type="checkbox"/>	Dry before use Temperature: __°C time: __hrs vacuum: _____ mm Hg: ____ desiccant: _____
<input type="checkbox"/>	Do not dry, correct for volatiles (___ LOD) or correct for moisture (___ KF)
<input type="checkbox"/>	Do not dry, use as-is
4 Sample preparation recommendations	
<input type="checkbox"/>	Use immediately (solutions are unstable)
<input type="checkbox"/>	Protect from light
<input type="checkbox"/>	Refrigerate
<input type="checkbox"/>	Other _____
5 Material information	
<input type="checkbox"/>	Material is stable under stated storage conditions for _____ years
<input type="checkbox"/>	Material is hygroscopic
<input type="checkbox"/>	Material is air sensitive
<input type="checkbox"/>	Material is light sensitive
6 Packaging recommendations	
<input type="checkbox"/>	Ambient temperature and humidity conditions
<input type="checkbox"/>	Rooms with a reduced relative humidity
<input type="checkbox"/>	Inert gas-filled glove box
<input type="checkbox"/>	Package under low actinic light