



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, excipient, or food ingredient, and 25 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.

Origin information (requested on questionnaire) is required. USP requires BSE-TSE statements for products that are animal derived, or use animal derived products in their process.

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. Donors also become eligible for USP's Donor Recognition Program, details of which are described on USP's website.



Candidate Material for USP Reference Standard Shipping Requirements

Please include the following in your USP Reference Standard candidate bulk material shipment:

1. Completed USP Reference Material Information Form
2. Certificate of Analysis for specific reference material candidate lot
3. Material Safety Data Sheet (MSDS)
4. Supporting data, spectra, chromatograms etc.
5. BSE-TSE Statement (for animal derived/comingled products)



Form B STA-4205-04

REFERENCE MATERIAL INFORMATION FORM

1. Reference Material Information

Reference Standard Candidate Name: _____

CAS Registry Number (if available): _____ Supplier lot/Batch number: _____

2. Supplier Information

Supplier: _____

Contact Name: _____

Phone number: _____ E-mail address: _____

Signature: _____ Date: _____

3. Origin of Material - REQUIRED

Country of Manufacture: _____

Synthetically Derived? Yes No

Animal Derived? Yes No

Animal type/organ/fluid: _____

Were any animal materials used in the processing of intermediates or final product? Yes No

Biologically Derived? Yes No
Source (e.g., fermentation, recombinant (provide expression system, e.g., plasmid, E. coli, CHO cells)): _____

Human Derived? Yes No

Fluid type: _____

Plant Derived? Yes No

Type/Part: _____

4. 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: _____



5. 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 _____
<input type="checkbox"/>	Not known
6. 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
<input type="checkbox"/>	Not known
7. 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 _____
<input type="checkbox"/>	Not known
8. 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
<input type="checkbox"/>	Not known
9. 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
<input type="checkbox"/>	Not known
10. Shipping Documentation	
<input type="checkbox"/>	Certificate of Analysis (CoA)
<input type="checkbox"/>	Material Safety Data Sheet (MSDS)
<input type="checkbox"/>	Supporting analytical data
<input type="checkbox"/>	BSE-TSE Letter (applicable only if animal derived, or if materials (e.g., organs, fluids, cells) from animals were used in (raw) material production or purification)
<input type="checkbox"/>	Harmonized Tariff Schedule (HTS Code) (optional) _____
<input type="checkbox"/>	NAFTA/FTA Certificates (optional)
<input type="checkbox"/>	FDA Product Code (optional) _____