



**Title: Using the Part Number/Master Specification Program to Establish
Raw Material Part Numbers and Master Specifications**

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1.0 Purpose

This procedure provides instruction on using the Part Number/Master Specification (PN/MS) software program for establishing or revising Part Numbers and Master Specifications for raw materials and components.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract

2.0 Scope

This procedure is applicable to Biopharmaceutical Development Program (BDP) personnel who will initiate or revise Part Number requests and establish specifications for raw materials and components.

NOTE: Refer to ***SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials*** for assistance in completing the Part Number and Master Specification forms. **Adobe Acrobat 10.0 Standard or Professional is required to have full use of the functions of this program.**

3.0 Authority and Responsibility

- 3.1 The Program and Technical Director, BDP has the authority to define this procedure.
- 3.2 BDP personnel are responsible for:
 - 3.2.1 Initiating Part Number (PN) Requests and determining the Master Specifications (MS).
 - 3.2.2 Completing the Part Number and Master Specification Request Forms (Attachments 4 and 5) in their entirety and obtaining approvals.
- 3.3 Biopharmaceutical Process Analytics / Quality Control (PA/QC) is responsible for:
 - 3.3.1 Review and approval of Master Specifications.
- 3.4 Biopharmaceutical Quality Assurance (BQA) is responsible for:
 - 3.4.1 Review and approval of the Part Number Requests and Master Specifications.
 - 3.4.2 Printing a hard copy of the electronically approved Part Number/Master Specification form and routing it to the requestor and approvers.
 - 3.4.3 Recording approval of the Part Number/Master Specification form in the Part Number/Master Specification program to permit the information to be automatically uploaded into the pcMRP database.
 - 3.4.4 Scanning the approved form within the Part Number/Master Specification Program.
 - 3.4.5 Quality oversight of this procedure.

4.0 Abbreviations

- 4.1 BQA – Biopharmaceutical Quality Assurance
- 4.2 PA / QC – Process Analytics / Quality Control
- 4.3 BQA – Biopharmaceutical Quality Assurance
- 4.4 COA – Certificate of Analysis
- 4.5 COI – Certificate of Irradiation
- 4.6 COO – Certificate of Origin
- 4.7 MMIC – Materials Management and Inventory Control

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract XXXXXXXXXX.

- 4.8 MS – Master Specification
- 4.9 MSDS – Material Safety Data Sheet
- 4.10 PN – Part Number

5.0 Overview of the Process

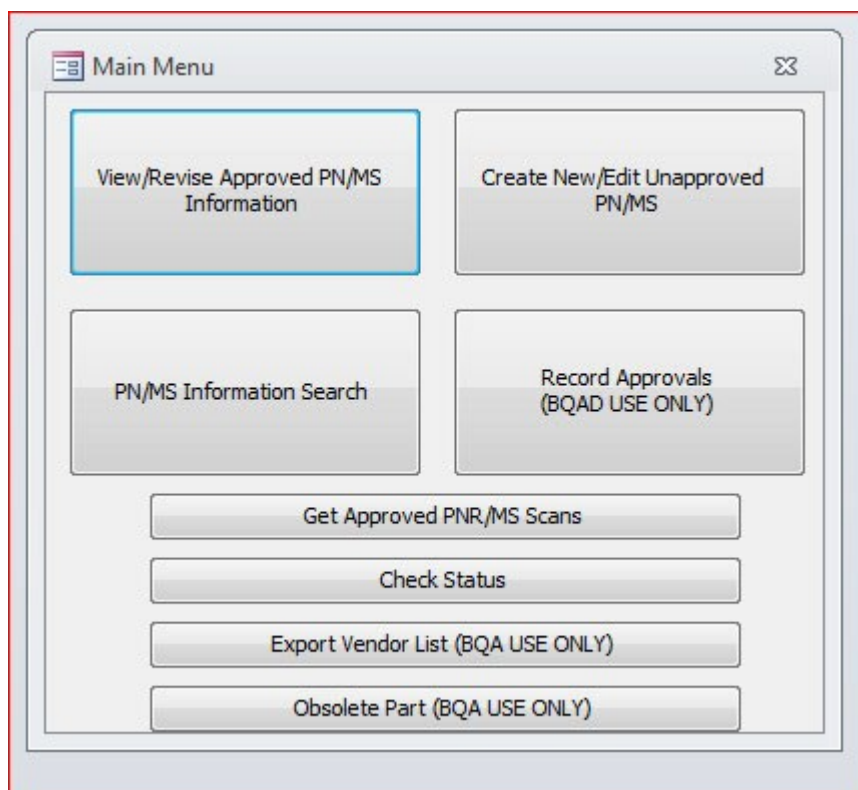
- 5.1 A request for a Part Number and Master Specification is initiated by using the Part Number/ Master Specification program located at [REDACTED]. This is a Microsoft Access program that allows information to be entered into a form electronically, review of entered information and generation of printed documents for final signature.
- 5.2 The required information is entered for the Part Number and Master Specification (if required) and routed electronically for review.
- 5.3 If the request is an A, E or F item, the information is sent for review and approval to BQA only. If a Master Specification is included (needed for B, C and D items), the documents are first routed to PA/QC for review.
- 5.4 Any BQA or PA/QC comments are incorporated into the form(s) by the requestor. When the information has been approved by the reviewers, BQA sends a hard copy of each form to the requestor for signature. The requestor sends the signed copy back to BQA and it is routed to PA/QC and BQA for signature(s).
- 5.5 When the approved signed document is received in BQA, the following will occur:
 - 5.5.1 The approval is recorded, prompting the Part Number/Master Specification program to automatically send an e-mail to the requestor, PA/QC and MMIC.
 - 5.5.2 The information is automatically uploaded into the pcMRP database. The database may be accessed at [REDACTED] (**SOP 20309 - Ordering Inventoried Materials Using the pc/MRP Inventory System**)
 - 5.5.3 BQA scans the approved document(s) within the Part Number/Master Specification program. The scanned approved document can be accessed by selecting "Get Approved PNR/MS Scans" within the program.
 - 5.5.4 The original is placed in the Part Number folder in the documents room for permanent storage in BQA Archives. This hand-signed form is the GMP controlled document.

6.0 Entering a New Record

NOTE: Refer to Attachments 1, 2 and 3

- 6.1 To initiate a request for a new Part Number, open the program located at [REDACTED].
- 6.2 The first screen (see Figure 1 below) will have a menu with the following selection of options to choose from: **"View/Revise Approved PN/MS Information," "Create New/Edit Unapproved PN/MS," "PN/MS Information Search," "Record Approvals (BQAD USE ONLY)," "Get Approved PNR/MS Scans", "Check Status", "Export Vendor List" and " Obsolete Part (BQA Use Only)".**

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**Figure 1**

View/Revise Approved PN/MS Information is used to view approved part numbers and make a revision to an approved Part Number/Master Specification.

Create New/Edit Unapproved PN/MS is used to establish a new part number and specification (if required). A revision may be made to an unapproved record from this screen. An unapproved part number may also be any part number that has not been entered into the Part Number program before.

PN/MS Information Search is used to find part numbers based on search criteria with the option to export the information to an Excel file.

Record Approvals (BQAD USE ONLY) is used by BQAD to record the final approval of a part number and/or specification in BQA, pcMRP and the PN/MS Program.

Get Approved PNR/MS Scans is used to retrieve a copy of the current approved Part Number form and/or Master Specification without having to open a record.

Check Status is used to check the approval status of a part number.

Export Vendor List (BQA USE ONLY) is used by BQA to export pre-selected fields from the PN/MS database to an Excel spreadsheet.

- 6.3 **Obsolete Part (BQA USE ONLY)** is used by BQA to obsolete pre-selected part numbers from the PN/MS database. Select the **“Create New/Edit Unapproved PN/MS”**

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button. On the next screen click on the "NEW" button next to the Part Number field on the upper left of the screen if a part number does not exist. A part entry dialog box will be displayed. The box has a pull-down menu for selecting the Class and a Description. Enter the requested information and select **OK**.

- 6.4 Once the information is entered from Section 6.3, the system assigns a new Part Number at revision level "0" and stores the Class and Description.

NOTE: It is helpful to write down the part number for future reference **before** closing the record.

- 6.5 A screen is displayed containing two tabs at the top. The first tab is for Part Number request information and the second tab is for Ordering Information (See Attachments 1 and 2). If B, C or D is entered for the inspection level in the Part Number screen, a third tab will appear for Master Specification information (See Attachment 3). All fields are initially empty except for the Part Number, Revision, Description and Class. Only the Part Number field is locked and cannot be changed.

The required information is entered into each screen. When the form is closed without submitting it, whatever information was entered is saved and may be recalled at a later time for additional editing. The following rules apply:

- The description cannot be identical to an existing description within the same class.
- The Abbreviated Description field will only accept a maximum of 15 characters.
- If level B, C or D is selected, a COA is required for each manufacturer listed.
- If level E is selected, a NDC number must be specified.
- If level F is selected, a COA is required for each lot received, but a sample COA may not be available when the PNR is being submitted. Attach if available, but it is not required.
- If the COO-eligible question is "Yes," a COO is required for each manufacturer listed.

NOTE: If a Usage, Sample Size, Retention Sample Size, or Manufacturer is entered that is not already in the list, it will be added automatically to the drop-down box as a selection by the program.

- 6.6 Proceed to the Ordering Information tab to complete the required Information. To enter a Manufacturer/Size, select the **Add** button in the Ordering Information field. A window will appear to enter the Manufacturer, Units, and Catalog Number. Select "OK" to save the information. All fields must be filled in. If more than one manufacturer is desired, continue to enter information into the pop-up window (this window will continue to pop-up each time OK is selected). When the fields for Manufacturer and Size populate the pMRRP suffix will be assigned.

- 6.6.1 In some cases when a custom or special order is placed with a manufacturer and there are multiple sizes or strengths, the manufacturer may not assign a unique catalog number to each item. If this is the case, each item when entered into the PN/MS program must have a unique catalog number.

Assign a suffix to the catalog number for each item when entering the information into the request form.

Example: Ad5 2 X 10¹¹ standard and Ad5 5 X 10⁹ standard were issued catalog number 79993 by the manufacturer. Suffix -1 and -2 or other appropriate designation should be added to the manufacturer catalog number.

- 6.6.2 Any complex, multi-component material (i.e. – dehydrated tissue culture media) should be ordered in quantities below 15kg if at all possible to enable the mixing of the material prior to QC sampling for release. If there is no alternative sizes available, a comment will be made in the master specification that a sample thief will be used for sampling the material.
- 6.7 When all information in Section 6.6 has been entered, select **Cancel** to continue filling out the rest of the Order Information form. Selecting **Cancel** will only remove the pop-up box. It will not delete any entered information.
- 6.8 In the bottom section of the Order Information form, select from the drop-down menu the release requirements set for each manufacturer. If the part is a B, C or D level select the **COA**, **COO** and **MSDS** (if required) buttons to electronically add the document. Attached files may be verified by clicking on the **View** button and must be in pdf format.
- NOTE:** COA's, COO's and MSDS's need to be scanned as an electronic copy if a pdf file is not already available. These documents are scanned to a location of the requestor's choice using one of the BDP scanners. When the **COA**, **COO** and **MSDS** buttons are selected, a screen will open to locate the file path of the scanned document.
- 6.9 If level B, C or D was selected in the Part Number form, complete the Master Specification form.
- 6.9.1 Complete the information in the 9 fields at the top of the form. Refer to **SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials** to complete this form.
- 6.9.2 To enter COA tests, select the **Add** button next to the COA Tests field.
- 6.9.3 Enter the test and criteria in the pop-up box that appears when **Add** is selected. When all COA tests are entered select the **Cancel** button. Selecting **Cancel** will only remove the pop-up box. It will not delete any entered information.
- NOTE:** To add a symbol or character to a test field right click on the mouse and select Character Map. Use the copy and paste functions to add the selection. Characters such as “/, \, [.]” cannot be used in the program.
- 6.10 To enter an In-House test, select the **Add** button next to the In-House Tests field. Select the test from the drop-down menu. If the test is not listed, it may be typed in. If the test is selected from the drop-down menu the SOP number will automatically be added to the SOP field. Type in the release criteria for the test.
- 6.11 When all tests are entered select the **Cancel** button to continue. Selecting **Cancel** will only remove the pop-up box. It will not remove any entered information.

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- 6.12 When all the information has been entered select the **Submit** button to save the information and complete the electronic approval process. The name of the requestor and the date will be linked to the request. If information is missing a pop-up box will appear to indicate what information is still required before the record can be submitted.
- 6.13 The electronic document will then be routed via email to PA/QC for review and approval (B, C or D level items only). If the requested part is an A, E or F item, it will be routed to BQA only for review and approval. If PA/QC approves the document, it is routed electronically to BQA for review and approval.
- 6.14 If the record is not approved by either PA or BQA, an email is sent back to the requestor with comments and/or requested changes. Refer to Section 9.0 for making revisions.

NOTE: BQA and PA/QC reviewers may print the forms to review them by selecting the **Create Forms** button.

7.0 Final Approval

- 7.1 When the document is electronically approved, BQA prints out the part number/master specification and any associated supporting documents for approval signature.
- 7.2 When PA/QC and BQA have signed the documentation, it is sent to BQA for processing and filing.

8.0 Recording the Approved Version

- 8.1 The signed approved Part Number form and the Master Specification form are scanned to a file server location.
 - 8.1.1 The Part Number Request scan will include the part number, revision page (if applicable), COA, COI, COO and/or other supporting documentation.
 - 8.1.2 The Master Specification form is scanned separately from the part number request and does not include any attachments.
- 8.2 After scanning the documents, BQA will enter the Part Number/Master Specification program and select "**Record Approvals (BQAD USE ONLY)**" from the main menu. A list of approved records will be displayed in the pop-up window. BQA will select records that have been received and selects **OK**, BQA links the Part Number Request and the Master Specification.
- 8.3 The Part Number/Master Specification program records the approved version as the current version and updates the pcMRP database with the information.
- 8.4 The PN/MS Program will notify the originator of the document, PA/QC and MMIC by email that the document has been approved and will supply a link to the location of the scanned copy.
- 8.5 BQA will place the signed document in the Part Number folder located in BQA archives for permanent storage.

9.0 Revisions

- 9.1 Revising a Rejected New Request

- 9.1.1 Open the Part Number/Master Specification program and select the **Create New/Edit Unapproved PN/MS** button. The record will be presented with a **“Re-Submit”** button.
- 9.1.2 Edit the information and select the **Re-Submit** button. The document will route again for electronic approval as in Section 6.13. Revising an Approved Record
- 9.1.3 Open the Part Number/Master Specification program and select the **“View/Revise Approved PN/MS Information”** button.
- 9.1.4 Enter the Part Number in the Part Number field and press ENTER. The form will be populated with the approved part information.
- 9.1.5 Press the **Revise** button in the upper left corner of the form. A new, editable record is created with the revision number incremented to the next sequential number.
- 9.1.6 When all revisions are completed select the **Reason for Revision/Revision Summary** button at the bottom of the screen. A revision box will appear to record the revisions made. Record what revisions were made in the lower section of the box. Once the revisions are recorded, click **OK**. The **Submit** button may now be selected to route the document for approval. The document will route for electronic approval as described in Sections 6.12 to 6.13.

NOTE: (For all revisions)

- Buttons are available on the upper left side of the record screens to view the approved part number form or master specification form.
- If the record is closed without submitting, the edits are discarded and the record remains in its previous state.
- Upon re-submission, all previous reviews and rejections are rescinded and the review process starts over as specified in Section 6.12 to 6.13.
- If a manufacturer is removed, the size information for that manufacturer will remain in the size field. It cannot be removed by the requestor.
- For B, C and D level items the COA, COO (if required) and MSDS (if required) will need to be re-scanned if the revision being made is a reflection of a change in one or more of these documents. If the revision was not done previously in the PN/MS Program all supporting documentation must be scanned in again.
- To change the order of the manufacturers, select the **Up** or **Down** buttons.
- If the record was initiated previously by someone other than the person editing the record, the person who performed the most recent previous edit to the current session is notified by email that the information has been changed.

- If a record is re-submitted while it is under review, any prior approvals are rescinded, and the current reviewers are notified by e-mail that the review request has been rescinded.

10.0 Cloning the Record

In some instances, a series of raw materials may vary only slightly. An example of this would be color, material of construction or description. To save time entering all the information for each part a record may be “cloned” so that only the difference between each item is changed in the cloned record. **Cloned records must be in the same class as the original part number.**

- 10.1 To reproduce (clone) a record, use the **Clone** button available in the **Create New/Edit Unapproved PN/MS** screen or the **View/Revise Approved PN/MS Information** screen on the lower left side of the record.
- 10.2 When all information is entered for the new or revised part number, select the Clone button. A new record will be generated with the next available part number.
- 10.3 Enter the information. If more then one cloned record is needed continue to select “Clone.”
- 10.4 As each record closes when it is submitted for approval the previous cloned record will appear. Each record can be submitted when completed or all records may be completed first and then submitted.

NOTE: Record the PN of each record for future reference before closing the screen.

11.0 Viewing Approved Part Number/Master Specification Information

- 11.1 Open the Part Number/Master Specification program and select the **“View Approved PN/MS Information”** button.
- 11.2 Enter the Part Number in the Part Number field and select Enter. The form will present the information on the approved Part Number. If the Part Number entered has not been approved using the PN/MS program a message will be displayed “Approved information does not exist”.
- 11.3 To view the scanned copy of an approved part number and/or master specification they may be accessed by using the main menu button labeled “Get Approved PNR/MS Scan”.

12.0 Searching for and Exporting Part Number Information

- 12.1 Open the Part Number/Master Specification program and select the **“PN/MS Information Search”** button.
- 12.2 A pop-up window will appear with search criteria for Part Number, Description, Manufacturer, Manufacturer’s Part Number, Class and Inspection Level.
- 12.3 Enter the information for the search into the field(s) and click **OK**.
- 12.4 The program will display a list of matches, containing the search criteria and number of records returned. The list itself consists of the Part Number, Description, approved revision number and pending revision number. The current approved revision and

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pending revision (if the document is being revised) may be viewed by selecting the corresponding buttons on the right side of the list.

NOTE: If the part number was initiated or revised through the PN/MS Program the complete information will be available. If the part number was initiated or revised prior to the initiation of the Part Number program, only partial information may be available. If this occurs the information on the part is available by looking at the scanned copy on BDP Public. The search field is not linked to existing scanned documents.

If only **OK** is selected in the search window a list of all the Part Numbers will appear.

- 12.5 The list of Part Numbers that result from a search may be exported to an Excel file by selecting the **Export** button at the bottom of the screen.

13.0 References and Related Documents

- 13.1 **SOP 21902** *Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials*
- 13.2 **SOP 20309** *Ordering Inventoried Materials Using the pc/MRP Inventory System*

14.0 Attachments

- 14.1 **Attachment 1** Part Number Screen
- 14.2 **Attachment 2** Ordering Information Screen
- 14.3 **Attachment 3** Master Specification Screen
- 14.4 **Attachment 4** Form 21903-01, Part Number Request
- 14.5 **Attachment 5** Form 21903-02, Master Specification Request

Attachment 1

Part Number Screen

The screenshot displays a web-based form titled "Part Information" with a standard window interface (minimize, maximize, close buttons). The form is divided into several sections:

- Navigation Tabs:** "Approved PNR", "Approved MS", "Part Number Request" (active), "Ordering Info", and "Master Specification".
- Part Identification:** Includes fields for "Part#:" (30430), "Revision:" (2), and "Class:" (30000- Reagents, Standards). Buttons for "New" and "Change" are present.
- Description:** A text field for "Description:" containing "Sucrose, NIST Standard Reference Material 17f".
- pcMRP Description:** A text field containing "Sucrose NIST".
- Product Attributes:** Radio buttons for "Product Contact?" (Yes/No, with "No" selected) and "Sterile?" (Yes/No, with "No" selected).
- Usage:** A dropdown menu showing "TOC testing" with an asterisk indicating a required field.
- Construction:** A text field containing "NA".
- CAS#:** A text field containing "57-50-1".
- Grade:** A text field containing "NIST".
- Shelf Life:** A dropdown menu showing "Vendor-assigned".
- Level:** A dropdown menu showing "B".
- Storage:** A dropdown menu showing "ambient".
- Is Item a Product-Contact Chemical, Resin, Filter, Media, Cell Line or Buffer?:** A dropdown menu showing "No".
- Required Documentation:** Radio buttons for "COA/COC" (selected), "COO", and "Diagram". An "Attach" button is next to the "Diagram" option.
- Comments:** A text area containing "NA".
- Footer:** Includes a "Clone" button, a "Reason for Revision" button, a "Revision Summary" button, and a "Re-submit" button.

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Attachment 2

Ordering Information Screen

The screenshot displays the 'Part Information' window with the 'Ordering Info' tab selected. It contains several sections for managing part specifications.

Ordering Information: Includes 'Add' and 'Remove' buttons and a table with columns: pcMRP Suffix, Manufacturer, and Catalog#.

pcMRP Suffix	Manufacturer	Catalog#
1	NIST	17
3	USP	1623637

Sizes: Includes a table with columns: pcMRP Suffix and Size.

pcMRP Suffix	Size
1	60 g
2	1 Kg
3	100 mg

Manufacturers: Includes 'Up' and 'Down' buttons and a table with columns: Manufacturer, Release Requirements, COA/COC Signature, COA/COC, COO, and MSDS.

Manufacturer	Release Requirements	COA/COC Signature	COA/COC	COO	MSDS
USP	Certificate inspection, no testing required	Yes	View Attach	View Attach	View Attach
NIST	Certificate inspection, no testing required	No	View Attach	View Attach	View Attach

Bottom Section: Includes 'Reason for Revision', 'Revision Summary', and 'Re-submit' buttons.

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Attachment 3

Master Specification Screen

Part Information

Approved PNR | Approved MS

Part Number Request | Ordering Info | Master Specification

Chemical Formula/Composition: Formula Weight/Size:

Sample Size: *

Retention Size: * Retention Period:

Safety Information: * Comments:

COA/COC Tests: * Accepts custom values

Test Criteria

In-House Tests:

Reason for Revision | Revision Summary |

Attachment 4

Part Number Request

FNLCR, BDP

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Form Number: 21903-01

Part Number:

SOP Number: 21903

Revision:

Revision 06: June 19, 2019

Issue Date: **PART NUMBER REQUEST**Description: Department: Abbreviated Description: Product Contact: *Intended Use: Sterile: Material Of Construction: Grade: CAS Number: Manufacturer:

Size Codes

Size	Catalog#
<input type="text"/>	<input type="text"/>

Size ID	Size	Minimum
<input type="text"/>	<input type="text"/>	<input type="text"/>

Part Classification Type: Inspection Level: Shelf Life: Storage Requirements:

(Not to exceed vendor-assigned expiry)

Is item a product-contact chemical, resin, filter, media, cell line or buffer?

NOTE: IF YES, A COO OR ALTERNATIVE DOCUMENTATION IS REQUIRED. REFER TO SOP 21106.

Documentation Required (check all that apply)

☐ NACOA and/or COC ☐COO or Alternative Documentation ☐☐ DiagramComments: Requestor Signature/Date: BQA Signature/Date: This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract XXXXXXXXXX.

Attachment 5

Component/Material Master Specification

FNLCR, BDP

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Form Number: 21903-02

Part Number:

SOP Number: 21903

Revision:

Revision 06: June 19, 2019

Issue Date: Component/Material Master Specification

PART A

Description: Inspection Level: Manufacturer: Release Requirements: COA Signature Required:

Size	Catalog#
<input type="text"/>	<input type="text"/>

Grade: CAS Number: Chemical Formula/Composition: Formula Weight/Size: Storage Requirements: Shelf Life:

(Not to exceed vendor-assigned expiry)

PART B

The following tests must be verified from the manufacturer's certificates for each shipment received:

Test	Specification
<input type="text"/>	<input type="text"/>

Special Instructions: Requestor Signature/Date: QC Signature/Date: QA Signature/Date: This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract XXXXXXXXXX.