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1.0 Purpose

This SOP describes the assignment of part and lot numbers for solutions, buffers, and reagents manufactured in the chemistry area of the Biopharmaceutical Development Program (BDP) for internal use.

2.0 Scope

This procedure is to be followed by BDP personnel who request part and lot numbers for solutions, buffers, and reagents from the chemistry area of the BDP. This procedure does not apply to solutions, buffers, and reagents, which will be used as products, external to the BDP, e.g., product diluents, reconstitution buffers, etc. See ***SOP 21405 - Assigning and Requesting Lot Numbers for Products*** and ***SOP 21902 - Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials***.

3.0 Authority and Responsibility

3.1 The Director, Technical Operations, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 The Manager, Manufacturing Support Services, Technical Operations, BDP, is responsible for ensuring that BDP manufacturing personnel are trained in this procedure and reporting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 The Manager, Formulation and Filling, Technical Operations, BDP, or designee, is responsible for assigning the next sequential part number/lot number in the assigned series to the solution, buffer, or reagent.

3.4 BDP manufacturing personnel are responsible for completing the Request for Reagent Solution, Form 15107-01.

3.5 BQA is responsible for quality oversight of this operation.

4.0 Procedure

4.1 General

4.1.1 The Manager, Formulation and Filling, or designee, assigns part numbers and maintains the official list of numbers.

4.1.2 Obsolete Part Numbers and assigned Lot Numbers will not be re-issued.

4.2 How to Obtain a New Part Number

4.2.1 The requestor for a new buffer will complete Form 15107-01 following the procedure in ***SOP 15107 – Request for Reagent Solutions.*** The form will be given to the Manager, Aseptic Processing, or designee, without the Part Number assigned.

4.2.2 The Manager, Formulation and Filling, or designee, will assign Part Number based on the following categories.

Acid Solutions	46000 to 46099
Base Solutions	46100 to 46199
Column Preparation Solutions	46200 to 46999
Purification and Formulation Solutions	47000 to 49999

4.2.3 Personnel in the Chemistry department will check the PN list located on the computer in Public (H)/4LPS/LPS only/Manufacturing Public/Aseptic Processing/Part Number to determine if a part number has already been assigned for this formulation.

4.2.3.1 The file for Part Number includes Part Number, Name of Product and Date Part Number was assigned.

4.2.4 If the formulation is not in the system, the next available part number in the appropriate category will be assigned to the formulation by the Manager, Formulation and Filling, or designee.

4.2.5 Based on the information provided by the requestor, the Part Number will receive the following suffix designating the level of testing required.

4.2.5.1 R&D – Buffer will be used for Research or Development purposes only.

4.2.5.2 EDEV – Buffer will be used for Early Development purposes only.

4.2.5.3 CL – Used for Good Manufacturing Practices (GMP) production where the buffers or solutions will be used as cleaning solutions.

4.2.5.4 IP – Used for GMP production where the buffers or solutions will be used for product purification.

4.2.5.5 No suffix – Used for GMP production where the buffers or solutions may be used for final formulation buffer or other critical applications.

4.2.6 The same part number may be issued with R&D, EDEV, CL, IP or no suffix) (e.g., 46001 R&D, 46001 IP, or 46001 no suffix).

4.3 How to Obtain a Lot Number

4.3.1 Lot numbers for chemistry formulations are as follows.

40000 to 49999

4.3.2 The Lot Number list is located on the computer in Public (H)/ 4LPS/LPS only/Manufacturing Public/Aseptic Processing/Buffer Part and Lot Numbers. The next available sequential Lot number is assigned to the Chemistry Protocol.

4.3.3 The file for Lot Number includes:

4.3.3.1 Status

4.3.3.1.1 GMP (date when sent to QA changed to date released, when QA releases the product.)

4.3.3.1.2 IP Cl (sent to QA removed when QA signs off on BPR and date released by manufacturing.)

4.3.3.1.3 R&D (Date released by manufacturing.)

4.3.3.1.4 EDEV (Date released by Manufacturing)

4.3.3.2 Lot Number

4.3.3.3 Part Number

4.3.3.4 Project Number

4.3.3.5 Batch Size

4.3.3.6 Container Fill Volume

4.3.3.7 Product Description

4.3.3.8 Testing Category

4.3.3.9 Expiration Date Note: EDEV reagents will not be assigned expiry.

4.3.3.10 Date Lot Number issued.

5.0 Definitions

5.1 **Solutions Lot Number (Lot#) –** Five-digit number assigned for each new batch of buffer.

5.2 **Solutions Part Number (PN) –** A five-digit number (which may include a suffix) is assigned for each new formulation or to the current formulation if release specifications are changed. A suffix is used to indicate reduction in testing requirement for the release of the product.

5.2.1 CL – Cleaning Buffers/Solutions, used for GMP production where the buffers or solutions will be used as cleaning solutions.

5.2.2 IP – In Process buffer/solution; released by manufacturing after manufacturing review of the BPR, then reviewed by QA.

5.2.3 No Suffix – Final product buffers: reviewed by manufacturing and released by QA, then release sticker by manufacturing.

5.2.4 R&D – Released by manufacturing after manufacturing review of the BPR.

5.2.5 EDEV – Released by manufacturing after review of the BPR.

5.3 **Specification –** The quality parameters and results to which the products or materials must conform, and which serves as a basis for quality evaluation.

6.0 References and Related Documents

SOP 15107 *Request for Reagent Solutions*

SOP 20003 *Materials Management and Inventory Control (MMIC) Program*

SOP 20302 *Receipt and Inspection of Materials*

SOP 21405 *Assigning and Requesting Lot Numbers for Products*

SOP 21902 *Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials*

7.0 Change Summary