	STANDARD OPERATING PROCEDURE			
Discovery Labs	SOP No.:	SOP-QA-004-05	Effective Date:	01.01.2018
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TITLE: BATCH NUMBERING SYSTEM

1.0 PURPOSE:

To lay down the procedure for batch numbering system.

2.0 SCOPE:

The batch numbering system procedure is applicable for the batches manufactured like Intermediates, Finished Products, and Recovery solvents, Reprocess, Rework process and Water at Discovery.

3.0 RESPONSIBILITY:

3.1 It is the responsibility of the QA Personnel to assign the batch number

3.2 It is the responsibility of the respective departments to follow the batch numbering system

3.3 Head-QA/Designee approve and implementation of the procedure

4.0 DEFINITIONS:

Batch: A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. The batch size can be defined as a fixed quantity.

Batch Number or lot number: A unique combination of numbers, letters, and / or symbols that identifies a batch (or lot) and from which the production and the distribution history can be determined.

Intermediate: A material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API.

5.0 PROCEDURE :

5.1 Unique batch numbering system shall be defined and shall be followed for regular batches, Recovery, Reprocess, Rework and Crop Batches etc.,.

5.2 User department shall request for the required process document.

5.3 QA should assign unique batch numbers, product wise and the same shall be mentioned in BPR and also in respective issuance record.

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	A. Ravi	B. Satyam
Department	Quality Assurance	Quality Assurance	Quality Assurance

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5.4 QA shall print / manually write the batch number on document and shall provide the document to user for recording purpose.

5.5 Batch number shall start for every calendar year (1st January – 31st December) and the sequential number shall start from 001 for each product.

5.6 The product is manufactured for two locations of same company / customer; the numbering system shall be included with unit/location number of respective customer.

Example: DAH product is being manufactured for single customer - Mylan and being supplied for Mylan unit-01 and unit -08.

5.7 Batch numbering system for the batches as follows

5.7.1 For Intermediate or API Batch: PPP-A/YYNNN

PPP   : Product code. The list of product codes shall be appended to the SOP.

A   : Product Stage code

YY   : Last two digits of the year i.e. for the year 2018 the year code is '18'

NNN   : Sequential number starts from 001 for each product and stage

Example1: DAH-I/18001 Batch number assigned for Lopinavir stage-I in the year 2018.

5.7.2 For Intermediate or API Batches, where the same product is supplying for two different units of same customer, the second / additional unit numbering system as follows

PPP-A/ UN YYNNN

PPP   : Product code. The list of product codes shall be appended to the SOP.

A   : Product Stage code

UN   : Unit code i.e. U indicates "Unit: and "N" indicates unit no. 1, 2, 3 etc…

YY   : Last two digits of the year i.e. for the year 2018 the year code is '18'

NNN   : Sequential number starts from 001 for each product and stage

Example1 : DAH-I/U818001 Batch number assigned for Lopinavir stage-I in the year 2018.

	Prepared by	**Reviewed by**	**Approved by**
Sign & Date			
Name	Y. Samatha	A. Ravi	B. Satyam
Department	Quality Assurance	Quality Assurance	Quality Assurance

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5.7.3 For API final Stage Batch (Dispatch batch): PPP/YYNNN

PPP : Product code. The list of product codes shall be appended to the SOP.

YY : Last two digits of the year i.e. for the year 2018 the year code is '18'

NNN : Sequential number starts from 001 for each product and stage

Example1 : LOP/18001 Batch number assigned for Lopinavir stage-III (i.e. Lopinavir stage-III is final stage) in the year 2018.

5.7.4 For Reprocess and Rework batches

PPP-A/RR YYNNN

PPP : Product code. The list of product codes shall be appended to the SOP.

A : Product Stage code

RR : Process type i.e. RP indicates "Re-process" and "RW" indicates "Re-work"

YY : Last two digits of the calendar year i.e. for the year 2018 the year code is '18'

NNN : Sequential number starts from 001 for each product and stage

Example1 : DAH-I/RP18001 is the batch number assigned for DAH-I Reprocess.

Example1 : DAH-I/RW18001 Batch number assigned for DAH-I Rework in the year 2018.

If the product is supplied for multiple units of single customer, the unit code shall include next to product and stage code.

5.7.5 For Blending Batch:

PPP - A/BLYYNNN

PPP : Product code

A : Product stage

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	A. Ravi	B. Satyam
Department	Quality Assurance	Quality Assurance	Quality Assurance

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BL : Blending

YY : Last two digits of the calendar year i.e. for the year 2018 the year code is '18'

NNN : Sequential number starts from 001 for each product and stage

Example : DAH-II/BL18001 Blending Batch number assigned for Lopinavir stage-II in the month of January 2018.

If the product is supplied for multiple units of single customer, the unit code shall include next to product and stage code.

If the API final stage (Dispatch batch) code shall not be required.

Example: LOP/BL18001 Blending Batch number assigned for Lopinavir stage-III in the month of January 2018.

5.7.6 For Milling and Shifting Batch:

PPP - A/XYYNNN

PPP : Product code

A : Product stage

X : For Milling-M/ For Shifting-S

YY : Last two digits of the calendar year

NNN : Sequential batch number product wise

Example : DAH-II/M18001 Milling Batch number assigned for Lopinavir stage-II in the year 2018.

5.7.7 For Second crop Recovery Batch:

PPP – A /REYYNNN

PPP : Product code.

A : Product Stage code

RE : Crop recovery

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	A. Ravi	B. Satyam
Department	Quality Assurance	Quality Assurance	Quality Assurance

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YY   : Last two digits of the calendar year i.e. for the year 2018 the year code is '18'

NNN   : Sequential number starts from 001 for each product and stage

Example   : DAH-II/RE18001 Batch number assigned for Crop Recovery of Lopinavir stage-II in the year 2018.

5.7.8   For Recovery Solvent Batch numbering system, If generate through in-process

PPP – A /AAA/RS/YYNNN

PPP   : Product code

A   : Product Stage

RS   : Recovery solvent

AAA   : Solvent code (i.e. TOL: Toluene codes shall be as RM code list)

YY   : Last two digits of the calendar year

NNN   : Sequential batch number Product wise irrespective of regular batch number

Example   : DAH-II/TOL/RS/18001 Batch number Assigned for Recovery solvent of Lopinavir stage-II in the year 2018.

5.7.9   For Recovery Solvent Batch numbering system, if generate CF MLs, separation etc,

PPP – A /AAA/YYNNN

PPP   : Product code

A   : Product Stage

AAA   : Solvent code (i.e. TOL: Toluene codes shall be as RM code list)

YY   : Last two digits of the calendar year

NNN   : Sequential batch number Product wise irrespective of regular batch number

Example: DAH-II/TOL/18001 Batch number Assigned for Recovery solvent of Lopinavir stage-II in the year 2018.

5.7.10 For Equipment cleaning record batch numbering during product changeover;

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	A. Ravi	B. Satyam
Department	Quality Assurance	Quality Assurance	Quality Assurance

ECR/PCO-XX-YYNNN

ECR   : Equipment Cleaning Record

PCO   : Product change over

XX   : Equipment (i.e. RV: Reactor, CF: Centrifuge)

YY   : Last two digits of the calendar year

NNN   : Sequential batch number reactor wise.

Example: ECR/PCO-RV-18001

5.8   Water batch numbering system should be follows:

5.8.1   For Raw Water Batch numbering:

RWYYMMDD

RW   : Raw Water

YY   : Last two digits of the calendar year

MM   : Month of Water collection

DD   : Date of Water Collection

Example: RW180101 raw water batch number assigned in January 2018.

5.8.2   For PW Water Batch numbering:

PWYYMMDD

PW   : Potable Water

YY   : Last two digits of the calendar year

MM   : Month of Water collection

DD   : Date of Water Collection

Example   : PW180101 Potable water batch number assigned in January 2018.

5.9   The dispatch batch numbering system to fallowed and assigned for Dr. Reddy's Laboratories Limited products.

PPPANNNYYDI

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	A. Ravi	B. Satyam
Department	Quality Assurance	Quality Assurance	Quality Assurance

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PPP : Product code. The list of product codes shall be appended to the SOP.

A : Product Stage code

YY : Last two digits of the year i.e. for the year 2018 the year code is '18'

NNN : sequential number starts from 001 for each product and stage

DI : Refer code for Discovery Laboratories Pvt Ltd.

Example : AMT200118DI Batch number assigned for AMT stage-2 first batch in the year 2018.

6.0   FORMATS / ANNEXURE(S):

Product Code List   : QA004-FM143

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	A. Ravi	B. Satyam
Department	Quality Assurance	Quality Assurance	Quality Assurance

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7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01-06-2007	New SOP introduced.	---
01	01-07-2009	SOP format changed and reviewed for more clarity.	---
02	15.06.2014	Revised as per current SOP & more clarity.	---
03	01-01-2017	1. SOP format changed make to inline with SOP-QA-001-04. 2. Batch numbering system changed. 3. Recovery solvent batch numbering system included. 4. Batch numbering system included for milling and sifting. 5. Water batch numbering system altered. 6. Altogether procedure has been rephrased for better clarity.	QA-CRF-014/16
04	08.11.2017	1. SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/17028
05	01.01.2018	Equipment Cleaning Record Batch Numbering during Product Changeover has been changed.	CCF/GEN/17037

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	A. Ravi	B. Satyam
Department	Quality Assurance	Quality Assurance	Quality Assurance

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