



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Allotment of Batch Number	Effective Date:
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1.0 OBJECTIVE:

To lay down a procedure for allotment

2.0 SCOPE:

This SOP is applicable to the allotment of batch numbers, both fresh and reprocessed batch of different products manufactured at

3.0 RESPONSIBILITY:

QA Officer / Executive
Head - Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 QA shall be responsible for allotting the batch numbering pattern for a new product before the start of production.

5.2 The batch number of a product shall consist of following 5 digits.

WX YZZ

W	X	Y	ZZ
Alphabetic code of Product Name	Alphabetic/numeric code	Year	Serial No.

Where: First digit indicates to first alphabetic code of product name

X: Second digit indicates to Alphabetic/numeric code of different strength of same product.

Y : Third digit indicates last digit year of manufacturing

ZZ: Forth and fifth digits indicate sequential number of batch manufactured during the year.

(Incase of more than 99 batches in a year of particular product, three digits shall be used)

For Example -I:

OA 2101



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Where,

O: First letter of Ofloxacin tablet

A: Ofloxacin 100 tablet

22: Year of 2022

01: First batch of Ofloxacin 100 tablet in year 2022

For Example –II:

OB 2202

Where,

O: First letter of Ofloxacin tablet

B: Ofloxacin 200 tablet

22: Year of 2022

02: Second batch of Ofloxacin 200 tablet in year 2022

5.3 For combi packed Products (Containing more than one product packed together):

5.3.1 The batch number will start in ‘C’ series of product code and shall consist of following 5 digits.

CX YZZ

C	X	Y	ZZ
First Alphabet of Combi pack	Alphabetic/Numeric code	Year	Serial No.

Where,

C: First digit indicates to first Alphabetic code of Combi pack

X: Second digit indicates to alphabetic/Numeric code of the Combi pack.

Y: Third digit indicates last digit year of manufacturing

ZZ: Forth and fifth digits indicate sequential number of Combi pack manufactured during the year.

Example:

For packing of combi-pack of more than one product

CI2201



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Where

C: First alphabet of Combi pack

I : Alphabetic /Numeric code of combi packed products

22: Year of 2022

01: First batch of Combi packed products in 2022

5.4 For Common Blend (For more than one strength having linear formula):

The batch number shall start from 'B' and consist of following 5 digits

BXX YZZ

B	XX	Y	ZZ
First alphabet of Blend	Alphabetic/Numeric code	Year	Serial No.

Where,

B: First digit indicates of Blend

XX: Second and third digit indicates to Alphabetic/Numeric code of the product related to common blend

Y: Fourth digit indicates last digit year of manufacturing

ZZ: Fifth and sixth digits indicate sequential number of common blend manufactured during the year.

Example:

For Manufacturing of Common blend for Product (P) of R mg and S mg strengths.

B0A 2101

Where

B : First letter of Blend

01: Alphabetic/Numeric code for Product (A) for B mg and C mg.

21 : Year of 2021

01 : First Common blend in year 2021

5.5 A record of the identification codes of the products shall be maintained by the Quality Assurance department as per Annexure –II.

5.6 The list of the identification codes shall be revised at the incorporation of a new product.

5.7 In case of reprocessed batch, the batch number shall be suffixed with 'R'.



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- 5.8 The manufacturing date of the reprocessed batch shall be the current date at which reprocessing takes place and the expiry date shall be the expiry date of the original batch.
- 5.9 The Head QA shall verify the numbering pattern / code and check that the same number shall not be allotted for any other product from the list of the identification codes and shall approve as per Annexure-I
- 5.10 While issuing the BMR/BPR, the QA department shall ensure that the numbering pattern is maintained and the serial numbering of the batches is not deviated.

6.0 For Placebo Batch:

- 6.1 The Placebo batch number of the product shall consist of following 7 digits.

PBXYYZZ

PB	X	YY	ZZ
Placebo Batch	Hyphen	year	Serial No.

Where,

PB: First and Second digit indicates of Placebo Batch

X : third digit indicates to Hyphen

YY: Fourth and fifth digit indicates last digit year of manufacturing

ZZ : sixth and seventh digits indicate sequential number of Placebo Batch manufactured during the year.

Example

For First Placebo Batch in year 2021

PB -2101

Where

PB: Placebo Batch

- : Hyphen

21: Year 2021

01: First batch of Placebo in year 2021

7.0 ABBREVIATION(S):



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Annexure –I

BATCH NUMBERING PATTERN APPROVAL

From : QUALITY ASSURANCE			
Cc :			
Kindly allot a batch numbering pattern for the new product			
Product name			
Generic Name			
Formulation type	Tablets/Capsules/Granules/Injections/others; specify_____		
Strength			
Any other strengths for the same type of product			
Initiated by ->	Name	Signature	Date
QA Department			
TO BE FILLED BY QA DEPARTMENT			
Product batch numbering pattern allotted:			
Approval	Name	Signature	Date
Approved by (Head QA)			

