

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE Title: Code Change and Handling of Code Digit of BFS 603 Machine SOP No.: Department: Production Effective Date: Production Revision No.: 00 Revision Date: Supersede Revision No.: Nil Page No.: 1 of 5

1.0 OBJECTIVE:

To lay down a procedure for Code change and Handling of code digit of BFS 603 Machine.

2.0 SCOPE:

This SOP is applicable for the Code change and Handling of code digit of BFS 603 Machine (Make: Weiler engineering, Model: 603) in Production Area.

3.0 RESPONSIBILITY:

Officer / Operator - Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

- BFS Blow-Fill & Seal
- CIP Clean in Place
- Ltd. Limited
- No. Number
- Pvt Private
- QA Quality Assurance
- SIP Sterilization in Place
- SOP Standard Operating Procedure

6.0 **PROCEDURE**:

6.1 **PRECAUTION:**

- **6.1.1** Coding of bottles helpful to identification and differentiation of various products from one another and to avoid product mix up.
- **6.1.2** Code change shall be perform before starting CIP/SIP, new product, batch change over or whenever applicable.
- **6.1.3** Before remove of code magazine machine shall be in stop position.
- **6.1.4** Check & ensure main mold is in open position.
- 6.1.5 Remove the code no. magazine from the mould of all bottles.
- 6.1.6 Un-screw the edge plate of each magazine and remove previous digits from the magazine.
- **6.1.7** Insert new digit in the magazine after incorporating the code no.of the new product /batch as per **Annexure-II**.
- 6.1.8 Refit the edge plate of each magazine.
- **6.1.9** Fix all the set magazine in to the main mould.



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- **6.1.10** Take empty trial of 01 cycle (14 bottles) for code checking, after verifying through production & QA start the filling operation, record in BMR.
- **6.1.11** While handing the code digits, care to avoid any damage, since this may cause leakage/deformation in the bottle.
- **6.1.12** Proper handling shall be done previous code digits and new code digits (Total number of digits shall be accountable and store at machine tool room in supervision of production and QA chemist).
- 6.1.13 Code Numbering shall be done by following policy-

Code will be in 6 digits (As per machine mould)

PCMMYY, Where,

PC denoted as product code

MM denoted the month of manufacturing and,

YY denoted as product manufacturing year (Annexure-I)

For Example-product (Sodium chloride IP 0.9% w/v) having manufacturing date 02/2025 So product code will be 010225.

Note: - product code shall be cover to segregation of product generic name as well as any Formulation change.

For Example- product (metronidazole Infusion IP claim with 500 mg/100 ml with Sodium chloride 0.9% w/v) having manufacturing date 02/2025. So product code will be 020225.

If same product with different formulation (change in claim of sodium chloride IP)

Note: - New product code shall be added in annexure –I with change control. (*Code will be PCMMYY, where PC= product code.*)

7.0 **ANNEXURES:**

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Product code List for BFS 603 machine	
Annexure-II	CIP/SIP and Code Change Intimation Slip for BFS 603 Machine	

ENCLOSURES: SOP Training Record.

8.0 **DISTRIBUTION:**

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02
 Production
- Master Copy Quality Assurance



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9.0 **REFERENCES**:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE – I PRODUCT CODE LIST FOR BFS 603 MACHINE



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ANNEXURE – II CIP/SIP AND CODE CHANGE INTIMATION SLIP FOR BFS 603 MACHINE

From: production Chemist		To: Bottle Pack Operator
Product Name:		
Fill Volume: ML		
Batch No:		
New Code Number:		
Use Granules: Please carry out following process- Cleaning in place (CIP):	YES/NO	
Sterilization in place (SIP):	YES/NO	
Code change:	YES/NO	
Given By: (Production Chemist)	Date:	Time:
Verified By:	Date:	Time:
(QA Chemist)		
Received By:	Date:	Time:
(BP Operator)		