STANDARD OPERATING PROCEDURE

Title: Reconciliation of Batch (Semi-Finished Goods, Finished Goods & Secondary Packing Materials)

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 4	

1.0 OBJECTIVE:

To lay down a procedure for the Reconciliation of Batch (Semi-Finished Goods, Finished Goods & Secondary Packing Materials).

2.0 SCOPE:

This SOP is applicable for the Reconciliation of Batch (Semi-Finished Goods, Finished Goods & Secondary Packing Materials) in production area.

3.0 RESPONSIBILITY:

Officer / Executive - Production

4.0 ACCOUNTABILITY:

Head - Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
BPR	Batch Packing Records
BPCR	Batch Process Control Records
IPQA	In process Quality Assurance
IPQC	In process Quality Control
Ltd.	Limited
Pvt.	Private
SIP	Sterilization In Place
SPM	Secondary Packing Materials
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 RECONCILIATION OF SEMI-FINISHED GOODS:

6.1.1 Check and ensure that the filling operation is completed.

6.1.2 After completion of filling, record reconciliation of filled bottles in BMR/BPR. 'Reconciliation of Semi-Finished Goods'& record should be maintained in BPCR.

6.1.3 Write the actual batch size in column "1" of BMR/BPR, "**Reconciliation of Semi-Finished Goods**".

6.1.4 Write the quantity of No. of Good Bottles sends to Packing in column "2" refer Column "I" of clause no. 17.0

6.1.5 Write the quantity of Volume Adjustment & Initially filled Bottles Discard, (After BFS CIP & SIP) in column "3A"as shown in the clause no. 13.9.

6.1.6 Write the quantity of Bottles used for initial Volume checking (Prod. +IPQA) in column "3B" as shown in the clause no. 13.10.

6.1.7 Write the quantity of Rejection during Filling & Sealing in column "3C" as shown in the column "B" of clause no. 14.0.

6.1.8 Write the quantity of Solution Loss, during Filling +Mfg. in column "3D

6.1.9 Write the total quantity (3A+3B+3C+3D) in column No. "3E".

6.1.10 Write the quantity of Bulk Sample from mfg. in column 4A as shown in the column 3A of clause no. 11.0.

6.1.11 Write the quantity of Bottles used for Volume checking at every one hrs. By Prod. +IPQA in column 4B as shown in column (C+D) of clause no. 14.0.

6.1.12 Write the quantity of IPQC Sample (Initial+Middle+End) in column 4C as shown in the column 3B of clause no. 11.0.

6.1.13 Write the quantity of Validation Sample in column 4D.

6.1.14 Write the quantity of other sample in 4E if any.

6.1.15 Write the total quantity of sample (F) by adding 4A+4B+4C+4D+4E.

6.1.16 Write the total no. of filled bottles in column 5 by adding No. of Good Bottles + Total Samples.

6.1.17 Write the total Rejection or loss from column 3D.

6.1.18 Write the variance using formula [1-(5+6)] / 1*100, at column 7.

6.1.19 Note down calculation in BMR/BPR.

6.2 RECONCILIATION OF FINISHED GOODS (BATCH YIELD BPR):

6.2.1 Write the Theoretical quantity as per BMR.

6.2.2 Write the Standard Yield in (%)

6.2.3 Write the Actual Yield in (%)

6.2.4 Write the Quantity of Good Bottles Transferred from Packing To FG.

6.2.5 Write the Rejection during Leak Test.

6.2.6 Write the Rejection during Visual Inspection.

6.2.7 Write the Rejection during Packing (Flow Wrapping + Hi-cart).

6.2.8 Write the Q.C. Sample (Semi Finished + Finished Sample).

6.2.9 Write the In-process (IPQC + IPQA)

6.2.10 Write the Validation samples.

6.2.11 Write the Control Sample, Stability Sample, Ref. Sample.

6.2.12 Write the Total samples = Step 6a+6b+7a+7b

6.2.13 Write the Variance.

6.2.14 Note down calculation in BMR/BPR.

6.3 RECONCILIATION OF SECONDARY PACKING MATERIALS:

6.3.1 Follow clause 18 of BPR and Write down Quantity Issued of Secondary Packing materials (A).

6.3.2 Write Extra Qty. issued SPM (If any) (B).

6.3.3 Write Qty. Returned to Stores (C).

6.3.4 Write the Theoretical qty. consumed D by using formula D = (A+ B – C).

6.3.5 Write the Quantity Transferred to FG Store (E)

6.3.6 Write the Qty. Retained with BPCR (F)

6.3.7 Write the Finished Good sample (G)

6.3.8 Write the Stability Goods sample (H)

6.3.9 Write the Control Sample (I)

6.3.10 Write the Other Samples (J)

6.3.11 Write the Overprinted Material Destroyed (K)

6.3.12 Write the Rejected Quantity (L)

6.3.13 Write the Total M = (E + F + G + H + I + J+ K + L)

6.3.14 Write the % Variance = D–M/D X100

6.3.15 Write the Standard Limits for Variance (%)

6.3.16 Note down calculation in BMR/BPR.

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

- SOP, Titled **"Scrap Management"**.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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