STANDARD OPERATING PROCEDURE				
Title: In-Process Check During Large Volume Parenteral Filling & Sealing				
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 in-process check during Large Volume Parenteral Filling & Sealing.

2.0 SCOPE:

This SOP is applicable for the in-process check during Large Volume Parenteral Filling & Sealing in production area.

3.0 RESPONSIBILITY:

Officer/Executive - Production

4.0 ACCOUNTABILITY:

Head - Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
BFS	Blow Fill Seal
CIP	Cleaning In Place
IPQA	In-Process Quality Assurance
Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SIP	Sterilization In Place
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 PRE-CHECK BEFORE STARTING FILLING & IN-PROCESS:

6.1.1 Production Officer/Executive shall check the line-clearance as per check list mentioned in BMR.

6.1.2 Production Officer/Executive shall fill the details in line clearance check list and intimate to Officer/Executive QA person for approval.

6.1.3 Ensure the temperature and relative humidity of the area.

6.1.4 Record the machine parameter i.e. Extruder temperature, Hydraulic oil level, Hydraulic oil temperature, Hydraulic oil pressure, Chilled water temperature, Chilled water pressure and Air pressure.

6.1.5 Ensure the bulk solution is released from QC & release intimation attached into BMR.

6.1.6 Ensure the weighing balance, daily verification performed and verified by IPQA.

6.1.7 Ensure that calibrated measuring cylinder, blade, line Clarence tag, In-process sample label, black marker, vernier calipers, empty trolley for bottle rejection bin & waste bin (in-process solution discard) available for In-Process.

6.1.8 Now take line clearance for the filling activity.

6.2 EMPTY WEIGHT OF THE BOTTLES FROM EACH CAVITY:

6.2.1 After proper line clearance start the BFS machine, and take out 14 empty bottles (01 cycle) and check the following, Quality of bottles i.e.:

- Empty weight of bottle,
- Thickness,
- Hanger
- Shape of bottles.
- Tip of bottle

6.3 VERIFICATION OF BOTTLE CODE (FROM EACH CAVITY):

6.3.1 Check the product code, on the bottles, embossed on the bottle side. Verify the bottle code product wise from the reference SOP**.**

6.3.2 Product code should be in following format, PCMMYY where,

- Code will be in 6 digits (As per machine mould)
- PCMMYY, where PC denoted as product code
- MM denoted the manufacturing month.
- And YY denoted as product manufacturing year.

6.3.3 After checking all the parameter mentioned above, start the filling and set the standard filling volume & weight (using specific gravity of bulk) as per BMR. After setting standard fill volume, discard the first 05 cycles i.e. 14 x 5=70 bottles (in case of CIP/SIP of BFS machine).

6.4 MEASUREMENT OF GROSS WEIGHT & VOLUME OF INDIVIDUAL BOTTLES:

6.4.1 Take 14 bottles from each cavity of BFS filling m/c and take individual gross weight of each bottle and record the same in the BMR.

6.4.2 In case fill volume is not within specified limit, inform the BFS machine operator for the volume setting. After volume setting again take the 14 bottle from the filling line and take individual gross weight (in gm) of each bottle, record the weight in the BMR.

6.4.3 After that cut the 14 individual filled bottles from each cavity and measure the volume of solution (in ml), using calibrated measuring cylinder, and note down the volume in the BMR.

6.4.4 Check and record the bottle In-process environment parameter at every hours i.e.,

6.1.8.1 Record the Temp. RH -Filling area.

6.1.8.2 Volume- Standard volume as per BMR.

6.1.8.3 Bottle Quality – as per standard, mentioned in BMR.

6.1.8.4 Thickness - as per standard, mentioned in BMR.

6.1.8.5 Take the bottle thickness (in mm) from the three point of the bottles .i.e. from Top (Head), Middle (body) and bottom part of the bottle using venire calipers & record thickness in BMR.

6.4.5 Check all the in-process parameters at specified intervals and enter the details in BMR and in **Annexure No. – I**.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Record of In-Process During Filling & Sealing of Large Volume Parenteral product	

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:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

STANDARD OPERATING PROCEDURE				
Title: In-Process Check During Large Volume Parenteral Filling & Sealing				
SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	4 of 4	

ANNEXURE – I

RECORD OF IN-PROCESS DURING FILLING & SEALING OF LARGE VOLUME PARENTERAL PRODUCT

Block: …….. **Section:** Production

Date	Product	B. No.	Product code	B. Size (L)	Fill Volume (ml)	Specific Gravity (w/ml)
Fill weight (gm)	Min. weight		Average empty bottle weight (gm)	…….gm	Filling start time	……..
	Max. weight				Filling end time	…….
Done by Sign. (Prod.)			**Verified by Sign. (IPQA)**			

Block: …… **Section:** Production

Date	Product	B. No.	Product code	B. Size (L)	Fill Volume (ml)	Specific Gravity (w/ml)
Fill weight (gm)	Min. weight		Average empty bottle weight (gm)	…….gm	Filling start time	……..
	Max. weight				Filling end time	…….
Done by Sign. (Prod.)			**Verified by Sign. (IPQA)**			