STANDARD OPERATING PROCEDURE

Title: Batch Manufacturing at LVP Line

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 3	

1.0 OBJECTIVE:

To lay down a procedure for Batch Manufacturing at LVP Line.

2.0 SCOPE:

This SOP is applicable for Batch Manufacturing at LVP Line.

3.0 RESPONSIBILITY:

Operating Person - Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

Ar. No.	Analytical Reference No.
BMR	Batch Manufacturing Record
IPA	Iso Propyl Alcohol
Ltd	Limited
No.	Number
Pvt	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
WFI	Water for Injection
BET	Bacterial Endotoxin Test
RPM	Rotation Per Minute
PLC	Programmable Logic control

6.0 PROCEDURE:

6.1 Always follow Manufacturing instructions according to the respective BMR.

6.2 Ensure that Area is properly cleaned and free from the traces of Previous Material, containers and Documents.

6.3 Recheck the tags & gross weight of all the ingredients to be used for batch manufacturing & ensure that they match as per Raw material dispensing detail in BMR and Issue slip at DAY Store.

6.4 Ensure that the tank is Cleaned, Sterilized & the PLC of the Tank is working properly.

6.5 Check and ensure load cell, pH meter and DO meter verification done before Batch manufacturing.

6.6 Check the status board affix on room “Ready for Use”, also ensure that the bottom outlet valve of mixing tank is closed.

6.7 Calculate the actual requirement of WFI as per the standard batch size, collect the WFI in mixing tank, and send the sample to QC for chemical analysis, and BET after getting WFI sample report, start the stirrer & add ingredients one by one through the main hole of the tank as per instruction given in standard BMR.

Note: All batches WFI sample shall be send to QC for chemical and BET analysis.

6.8 Continue stirrer and circulation according to the Time and RPM specified in the respective BMR.

6.9 Stop the stirrer and circulation then make up the final volume as per required batch volume, with Water for Injection & check in load cell and dipstick scale (As per Annexure-II, of SOP.

6.10 Start the stirrer and circulation after volume make up for specific Time and RPM specified in BMR.

6.11 Intimate to QA collect bulk sample through sampling valve and send QC for analysis along with the bulk intimation slip.

6.12 After getting clearance of bulk analysis from QC, start the stirring and circulation at specified RPM and Time before filtration of the bulk solution in to Holding vessel.

6.13 After completion of pre-filtration repeat the step 6.8 to 6.13.

Note: In case of campaign batches flush the mixing vessels with tentative 100 L of WFI.

6.14 As per the Hold time study recommendations number of batches are to be manufactured in campaign mentioned in table below:

No. of Batches	Batch size	Per batch running time	Total run time for campaign.
02	4000 liters	14 hours	28 hours
03	3200 liters	12 hours	36 hours
03	2500 liters	09 hours	27 hours

Note: Campaign can be any batch size but running hours shall be as per the Hold time study, i.e. NMT 36 hours or NMT 03 batches of same molecules.

6.15 Pre integrity of all product filters (0.2 µ -Manufacturing and on BFS machine) shall be done in 1st batch of campaign at CIP/SIP and use photocopy for all campaign batches as a pre integrity. Then post integrity shall be perform after completion of the campaign batches, and attach the photocopy in filled batches BMR and also used as pre integrity for next campaign for same active molecule.

6.16 Pre-Integrity valid for 7 days only, new integrity required after 7 days for same molecule.

6.17 All the activities related to batch manufacturing shall be perform in presence of manufacturing chemist, operator and IPQA (whenever required).

6.18 Post CIP shall be perform for manufacturing, Holding vessels and BFS machine whenever next plan beyond 24 hrs. and repeat the same after 7 days interval if long production gap.

6.19 All the liquid items shall be dispensed and handle during manufacturing in only **SS316 L/Borosil Glass** container (HCL, Lactic acid).

6.20 Dilution for the pH adjustments (HCL, NaOH etc.) shall be prepared in **Borosil glass/SS316 L**.

6.21 If any material spillage or handling loss occurred during the dispensing or Batch manufacturing activities, report immediately and Hold it at same stage, after proper CAPA, shall be proceed for next stage .

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:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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