STANDARD OPERATING PROCEDURE

Title: Batch Manufacturing Procedure

SOP No.:		**Department:**	Production
		Effective Date:	
Revision No.:	00	**Revision Date:**	
Supersede Revision No.:	Nil	**Page No.:**	1 of 2

1.0 OBJECTIVE:

To lay down a Procedure for Batch Manufacturing.

2.0 SCOPE:

This SOP is applicable for the Batch Manufacturing.

3.0 RESPONSIBILITY:

Officer / Executive - Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
LAF	Laminar Air Flow
PLC	Programmable Logic Control
QA	Quality Assurance
QC	Quality Control
RM	Raw Material
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

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

6.2 Recheck the identification slip and weight of all the ingredients to be used for Batch Manufacturing and ensure that they match as per entries made in the RM weighing sheet of BMR.

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

6.4 Check & assure that Stirring, Jacket Cooling, Jacket Heating, and Temperature is being controlled by the PLC of the respective Tank.

6.5 Check and ensure load cell verification done before Batch manufacturing.

6.6 Check that the Bottom Outlet Valve of the Mixing Tank is closed.

6.7 Start the collection of WFI & send the sample to QC for Chemical, pH & conductivity.

6.8 On Approval of WFI Sample from QC Department, affix a Status Label on the Mixing Tank with Product Name, Batch No., Batch Size and Date.

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6.9 Collect Water for Injection in the Mixing Tank as per quantity mentioned in the BMR, start the Stirrer and add ingredients one by one as per instruction given in respective BMR.

6.10 Continue Stirring according to the time specified in respective BMR.

6.11 Stop the Stirrer.

6.12 Make up the Volume to the required Batch Size with Water for Injection by the gross weight shown in the display of the respective Tank's PLC display/ Dip Stick Mark.

6.13 Start the stirring and continue according to the time specified in BMR Intimate to QA Officer/Executive to collect Sample of Bulk Stage and send the sample for QC analysis (pH & Assay).

6.14 After getting clearance of bulk analysis from Quality control and instruction from manufacturing chemist start the Pre- Filtration of the Bulk solution.

6.15 PRECAUTIONS:

6.15.1 Always follow manufacturing instruction according to the respective BMR.

6.15.2 Prepare one batch at a time.

6.15.3 Calculate the final Volume as per the Specific Gravity of the Solution. (load cell)

6.15.4 In case of Campaign batches, WFI Sample will be send to QC, from first batch only.

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