PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Batch Manufacturing	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Batch Manufacturing.

2.0 SCOPE:

This SOP is applicable for Batch Manufacturing in production area at …….

3.0 RESPONSIBILITY:

Officer/Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 PRECAUTIONS:

6.1.1 Always follow manufacturing instructions according to the respective BMR.

6.1.2 Prepare One Batch at one time.

6.1.3 Calculate the final volume as per the specific gravity of the solution.

6.1.4 In case of preparation of suspensions ensure the proper working of LAF & start LAF 30 minutes before preparation of the batch.

6.2 Ensure that area is clean and free from previous product material, containers and documents.

6.3 Recheck the tags of all the ingredients to be used for batch manufacturing and ensure that they match as per entries made in the Raw Material dispensing details in BMR.

6.4 Ensure that the tank is clean & sterilized.

6.5 Check the status board affixed on the mixing tank "**Ready for Use"**, also verify the cleaning and sterilization records, Ensure that the bottom outlet valve of the mixing tank is closed.

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6.6 Collect water for Injection in the mixing tank as per quantity mentioned in the BMR, start the stirrer and add ingredients one by one through the main hole of the tank as per Standard Procedure for manufacturing of particular product mentioned in the BMR.

6.7 Send the WFI sample to Quality Control for testing.

6.8 On approval of WFI sample from QC department, affix a status board on the Mixing tank under manufacturing with Product Name, Batch No., Batch Size and Date.

6.9 Continue stirrer according to the time specified in respective BMR

6.10 Stop the stirrer.

6.11 Make up the volume to the required batch volume with Water for Injection & check in load cell.

6.12 Start the stirring after volume make up for time specified in BMR.

6.13 Intimate to QA collect bulk sample and send QC for analysis along with the bulk intimation slip.

6.14 After getting clearance of bulk analysis from Quality Control and instruction from Manufacturing Chemist, start the pre-filtration of the bulk solution.

7.0 ABBREVIATION:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number
WFI	Water for Injection
LAF	Laminar Air Flow
Mfg.	Manufacturing
QA	Quality Assurance
BMR	Batch manufacturing record
QC	Quality Control
Pvt.	Private limited

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8.0 ANNEXURES:

Not Applicable

9.0 DISTRIBUTION:

- Controlled Copy No.1 Production
- Controlled Copy No.2 Quality Assurance
- Master Copy Quality Assurance

10.0 REFERENCES:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		