

Sterile Manufacturing Production Batch Record

Product Name: _____

Batch Number: _____

Strength: _____

Batch Size: _____

Manufacturing Date: _____

Expiry Date: _____

1. Line Clearance

Area/Equipment	Cleaned (Yes/No)	Checked by (Initials)	Date/Time

Remarks:

2. Raw Material Dispensing

Material Name	Lot No.	Quantity Required	Quantity Dispensed	Dispensed By	Checked By

3. Manufacturing Process Details

Step	Procedure	Start Time	End Time	Performed By	Checked By
1					
2					

4. In-Process Checks

Parameter	Observation	Limit	Checked By	Date/Time

5. Sterilization Details

Cycle Number	Load Description	Start Time	End Time	Cycle Parameters	Performed By	Checked By

Comments:

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6. Yield Calculation

Theoretical Yield: _____

Actual Yield: _____

Yield % : _____

7. Final Review & Release

Reviewed By: _____

Released By: _____