

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:

6. Yield Calculation

Theoretical Yield: _____
Actual Yield: _____
Yield % : _____

7. Final Review & Release

Reviewed By: _____
Released By: _____