

# Batch Production Record (BPR)

## Sterile Injectable Products

Product Name:		Batch No.:	
Batch Size:		Batch Start Date:	
Manufacturing Date:		Expiry Date:	
Product Code:		Lot No.:	

### 1. Raw Material Details

Material Name	Lot/Batch No.	Manufacturer/Supplier	Quantity Required	Quantity Issued	Issued By (Signature/Date)	Checked By (Signature/Date)

### 2. Equipment & Area Preparation

Equipment/Area	ID No.	Cleaning Verified	Sanitization Verified	Checked By (Signature/Date)

### 3. Manufacturing Process

Step No.	Operation/Activity	Parameters/Observations	Time (Start/End)	Performed By	Checked By
1					
2					
3					

### 4. In-process Controls

Test/Parameter	Specification	Result	Tested By (Signature/Date)

### 5. Filtration & Filling

Filter Type/ID	Integrity Test	Filling Machine/ID	Remarks	Performed By	Checked By

### 6. Sterilization Parameters

Equipment	Cycle No.	Temperature (°C)	Pressure (bar)	Time (min)	Performed By	Checked By

7. Packaging & Labelling

Activity	Material/Lot No.	Quantity	Performed By	Checked By

8. Yield Calculation

Step	Theoretical Yield	Actual Yield	% Yield	Calculated By (Signature/Date)	Checked By (Signature/Date)

9. Remarks / Deviations / Notes

Description	Reviewed By (Signature/Date)

10. Batch Release

Prepared By:  

Date:

Reviewed By:  

Date:

Approved By:  

Date: