

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: