



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Hold Time Period of Bulk Solution and Filled Bottles

|                                |     |                        |            |
|--------------------------------|-----|------------------------|------------|
| <b>SOP No.:</b>                |     | <b>Department:</b>     | Production |
|                                |     | <b>Effective Date:</b> |            |
| <b>Revision No.:</b>           | 00  | <b>Revision Date:</b>  |            |
| <b>Supersede Revision No.:</b> | Nil | <b>Page No.:</b>       | 1 of 2     |

### 1.0 OBJECTIVE:

To lay down a procedure for Hold time period of bulk solution and filled bottles.

### 2.0 SCOPE:

This SOP is applicable for Hold time period of bulk solution and filled bottles in Production Area.

### 3.0 RESPONSIBILITY:

Officer / Executive Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBRIVATIONS:

|       |                                     |
|-------|-------------------------------------|
| Ltd   | Limited                             |
| NA    | Not Applicable                      |
| No.   | Number                              |
| PVT   | Private                             |
| SHWSS | Super-Heated Water Spray Sterilizer |
| SOP   | Standard Operating procedure        |

### 6.0 PROCEDURE:

#### 6.1 Hold time period of bulk solution and filled bottles:

**6.1.1** Maximum holding time of bulk solution in mixing tank is 24 hours.

**6.1.2** Maximum holding time of bulk solution after filtration 48 hours from the time of filtration up to time of filling of the last cycle i.e. end of the filling operation of a batch is 48 hours.

**6.1.3** In case, if the time exceeds 48 hours, the bulk solution should be drained out.

**6.1.4** In case of break down in SHWSS, filled bottles can be hold for 72 hrs, in case of routine production filled and sealed bottles can be hold for 48 hours.

### 7.0 ANNEXURES:

Not Applicable

**ENCLOSURES:** SOP Training Record.

### 8.0 DISTRIBUTION:

- Controlled Copy No.01                      Quality Assurance
- Controlled Copy No.02                      Production
- Master Copy                                      Quality Assurance

### 9.0 REFERENCES:

Not Applicable



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| <b>Supersede Revision No.:</b> | Nil | <b>Page No.:</b>       | 2 of 2     |  |

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

| Revision No. | Change control No. | Details of Changes | Reason for Change | Effective Date | Updated By |
|--------------|--------------------|--------------------|-------------------|----------------|------------|
|              |                    |                    |                   |                |            |