



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Replacement of Silicon Gaskets & TC Clamp Used In Product Line of Mixing Tank to Holding Tank & Holding Tank to BFS M/C In LVP Line

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 4

1.0 OBJECTIVE:

To lay down a procedure for replacement of silicon gaskets and TC clamp being used at different connecting points in product line of Mixing tank to Holding tank & Holding tanks to BFS m/c in LVP line.

2.0 SCOPE:

This SOP is applicable for replacement of silicon gaskets being used at different connecting points in product line of Mixing tank to Holding tank & Holding tanks to BFS m/c in LVP line.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBRIVATION:

BFS	Blow-Fill & Seal
CIP	Clean in Place
Ltd	Limited
LVP	Large Volume Parenteral
M/C	Machine
NA	Not Applicable
No.	Number
Pvt.	Private
QA	Quality Assurance
SIP	Sterilization in Place
SOP	Standard Operating procedure
TC	Tri Clove

6.0 PROCEDURE:

6.1 ENSURE THE AVAILABILITY OF THE FOLLOWING:

6.1.1 Silicon gaskets & TC Clamp of required sizes and quantity.

6.2 OPERATION OF REPLACEMENT OF SILICON GASKETS & TC CLAMP IN PRODUCT LINE OF MIXING TANK TO HOLDING TANK & HOLDING TANK TO BFS M/C IN LVP LINE:

6.2.1 During CIP Mixing Operator will open all the TC ends of SS pipe lines, filter housings & remove Silicon gaskets used in Mixing tank to Holding tank & Holding tank to BFS M/C .

6.2.2 Mixing Operator will clean the grooves of TC ends and clamps with nylon brush/lint free cloth & hot WFI, then replace all the silicon gaskets (Incase gasket damage, or physical appearance not ok, as well as change the TC clamp if found rusted) with new ones, during inspection if found any breakage in TC clamp change with new ones.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Replacement of Silicon Gaskets & TC Clamp Used In Product Line of Mixing Tank to Holding Tank & Holding Tank to BFS M/C In LVP Line

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	2 of 4	

6.2.3 Mixing Operator will tight all the open TC ends properly & ensure that it should not leak during the operation.

6.2.4 Then do CIP & SIP before taking a new batch on LVP line.

6.3 PRECAUTIONS:

6.3.1 Ensure that all opened joints are tightening properly & leak free.

6.3.2 Ensure that SS pipelines are not hot during replacement of gaskets & TC Clamp etc.

6.3.3 Mixing Operator will cut all the worn out gaskets with scissors & destroy it and old rusted and broken TC clamp to be changed with new one.

6.3.4 Record the Gasket & TC clamp replacement record during inspection in **Annexure-I**.

6.3.5 If any TC Gasket/TC Clamp/Diaphragm valve/Filling Head Diaphragm/Filter housing gasket 'O' Ring/Transfer Pump gasket 'O' Ring leakage or rupture change in running production , Change it with new one and CIP/SIP shall be taken before production start & related addition samples shall be sent for analysis.

6.4 FREQUENCY:

6.4.1 In LVP lines, replace the silicon gaskets after every three months or in case of media fill. It shall be replace after media fill.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Gasket & TC Clamp Replacement Records	

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



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Replacement of Silicon Gaskets & TC Clamp Used In Product Line of Mixing Tank to Holding Tank & Holding Tank to BFS M/C In LVP Line

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	3 of 4	

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Replacement of Silicon Gaskets & TC Clamp Used In Product Line of Mixing Tank to Holding Tank & Holding Tank to BFS M/C In LVP Line

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	4 of 4

ANNEXURE – I GASKET & TC CLAMP REPLACEMENT RECORDS

Frequency: Three Months or after Media Fill activity or whenever required.

S. No.	Location	No. of TC Gaskets	TC Clamp	Diaphragm Valve Gaskets	Filling Head diaphragm gaskets	Filter (Air + Solution) Housing Gaskets 'O' Rings	Transfer Pump Gaskets/ 'O' Ring	Replacement date	Done By	Checked by Sign & Date	Verified By Sign & Date
1.	Manufacturing to Holding Vessel	22 (1.5"), 07 (2"), 12 (1/2")	22 (1.5"), 07 (2"), 12 (1/2")	5 (1.5"), 2 (1"), 4 (2"), 4 (1/2")	NA	4 Air	2 Nos.				
					NA						
2.	Holding vessel to BFS Machine	19 (1/2"), 10 (2"), 54 (1.5")	19 (1/2"), 10 (2"), 54 (1.5")	12 (1/2"), 3 (2"), 17 (1.5")	NA	4 Air, 3 Solution	2 Nos.				
					NA						
3.	Filling Area	46 (1.5"), 65 (1/2")	46 (1.5"), 65 (1/2")	20 (1/2"), 2 (1"), 6 (1.5")	14 Nos.	5 Air, 2 Solution	NA				
							NA				

✓ Tick for Done