



Title: FDV Challenge Test for Purified Water and WFI System

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1.0 OBJECTIVE:

To lay down a Procedure for FDV challenge test for Purified Water and WFI System.

2.0 SCOPE:

This SOP is applicable for FDV challenge test for Purified Water return loop, EDI Permeate, MCDP outlet & WFI return loop.

3.0 RESPONSIBILITY:

Officer / Executive – Engineering

4.0 ACCOUNTABILITY:

Head – Engineering

5.0 ABBREVIATIONS:

FDV	Flow Diverging Valve.
SOP	Standard Operating Procedure
PW	Purified Water
WFI	Water for Injection
MCDP	Multi Column Distillation Plant
EDI	Electro Deionization
TOC	Total Organic Carbon
Cond.	Conductivity

6.0 PROCEDURE:

6.1 FDV challenge test activity shall be performed at the time of preventive maintenance with a frequency of quarterly.

6.2 FDV challenge test is done at manager or admin level password.

6.3 Run the system and observe the value of conductivity & TOC.

6.4 Conductivity Challenge test procedure:-

6.4.1 Set the conductivity at observed actual value then check the working of dumping valve. Dumping valve remains closed.

6.4.2 Then set the conductivity below actual reading of conductivity.



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6.4.3 Dumping Valve shall open and the water starts draining.

6.4.4 After 30 seconds of tests reset the conductivity as per set parameter.

6.5 TOC challenge test procedure:-

6.5.1 Set the TOC at observed actual value then check the working of dumping valve. Dumping valve remains closed.

6.5.2 Then set the TOC below actual reading of TOC.

6.5.3 Dumping Valve shall open and the water starts draining.

6.5.4 After 30 seconds of test reset the TOC value as per set parameter.

6.6 Record the FDV challenge test observation in **Annexure-I** "FDV Challenge Test for Purified Water and WFI System".

6.7 After successfully completing the challenge test of FDV affix the status label as per **Annexure -II** "Status Label".

6.8 Frequency: Once in 3 month \pm 7 days & whenever required.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	FDV challenge test for Purified water & WFI System	
Annexure-II	Status Label	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

HYDROPURE.



PHARMA DEVILS

ENGINEERING DEPARTMENT

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE – I
FDV CHALLENGE TEST FOR PURIFIED WATER AND WFI SYSTEM

Location:

Area:

Frequency:

S. No	Date	CONDUCTIVITY CHALLENGE TEST						TOC CHALLENGE TEST					Done By (Sign & Date)	Review By (Sign & Date)	
		Time		Cond. Observe	FDV function at Observe Cond.	Cond. set value	FDV Function at Set Value	Time		TOC Observe	FDV function at Observe TOC	TOC set value			FDV Function at Set valve
		From	To					From	To						
1.															
2.															
3.															

NOTE: - FDV FUNCTION RECODED AS OPEN/CLOSE

Remarks:-



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**ANNEXURE – II
STATUS LABEL**

STATUS LABEL
FDV ID:
CHALLENGE TEST DONE ON:
FREQUENCY:
CHALLENGE TEST NEXT DUE ON:
REMARKS:
CHECKED BY : (SIGN & DATE)