 Discovery Labs	STANDARD OPERATING PROCEDURE			
	SOP No.:	SOP-ED-020-00	Effective Date:	01.01.2018
	Supersedes :	Nil	Next Review Date:	31.12.2020
	Department:	Engineering	Page:	1 of 4
TITLE: OPERATION AND MAINTENANCE OF WATER SYSTEM				

1.0 PURPOSE:

To lay down the procedure for operation & maintenance of water system.

2.0 SCOPE:

This SOP is applicable to the available water system at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:


- 3.1 It is the responsibility of the Engineering department personnel to operate and maintain as per procedure described in this SOP.
- 3.2 It is responsibility of production department raise ATR to QC.
- 3.3 It is the responsibility of quality control department sampling and analyze the water sample.

4.0 DEFINITIONS: NIL

5.0 PROCEDURE :

- 5.1 This Source water shall be collected from underground storage tank.
- 5.2 The treated raw water shall be collected in the HDPE tank.
- 5.3 **Operating procedure:**
 - 5.3.1 Turn on Multi grade filter.
 - 5.3.2 Switch on the Raw water pump.
 - 5.3.3 Source water passes through the Multi grade filter (MGF) which contain 10 μ Candy filter and collect the water in HDPE storage tank
 - 5.3.4 Whenever required, ensure the Raw water level.
 - 5.3.5 Two distribution points are present in plant and each distribution point connected with candy filter (5 μ) followed by flow meter.
- 5.4 **Multi Grade Filter:**
 - 5.4.1 Multi grade filter remove the extraneous matter present in the water.
 - 5.4.2 If Multi grade filter become clogged after a period of usage, then back washed to remove clog.
 - 5.4.3 Switch on Multi grade backwash mode daily once as follows.

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- 5.4.4 Put multi-port valve on back wash mode, Open source water inlet valve.
- 5.4.5 Start the Source water pump.
- 5.4.6 Pass the water for 10-15 minutes through the multi grade filter and allow to drain.
- 5.4.7 After that, stop the source water pump and close the source water inlet valve.

5.5 **Water Batch Numbering System:**

The following pattern shall be followed for assigning In-house Batch number for water.

XXYYMMDD

Where;

XX Indicates water. (i.e.: SW is source water; RW is Raw water)

DD indicates date

MM indicates month,

YY indicates running year.


e.g.: SW180101 & RW180101

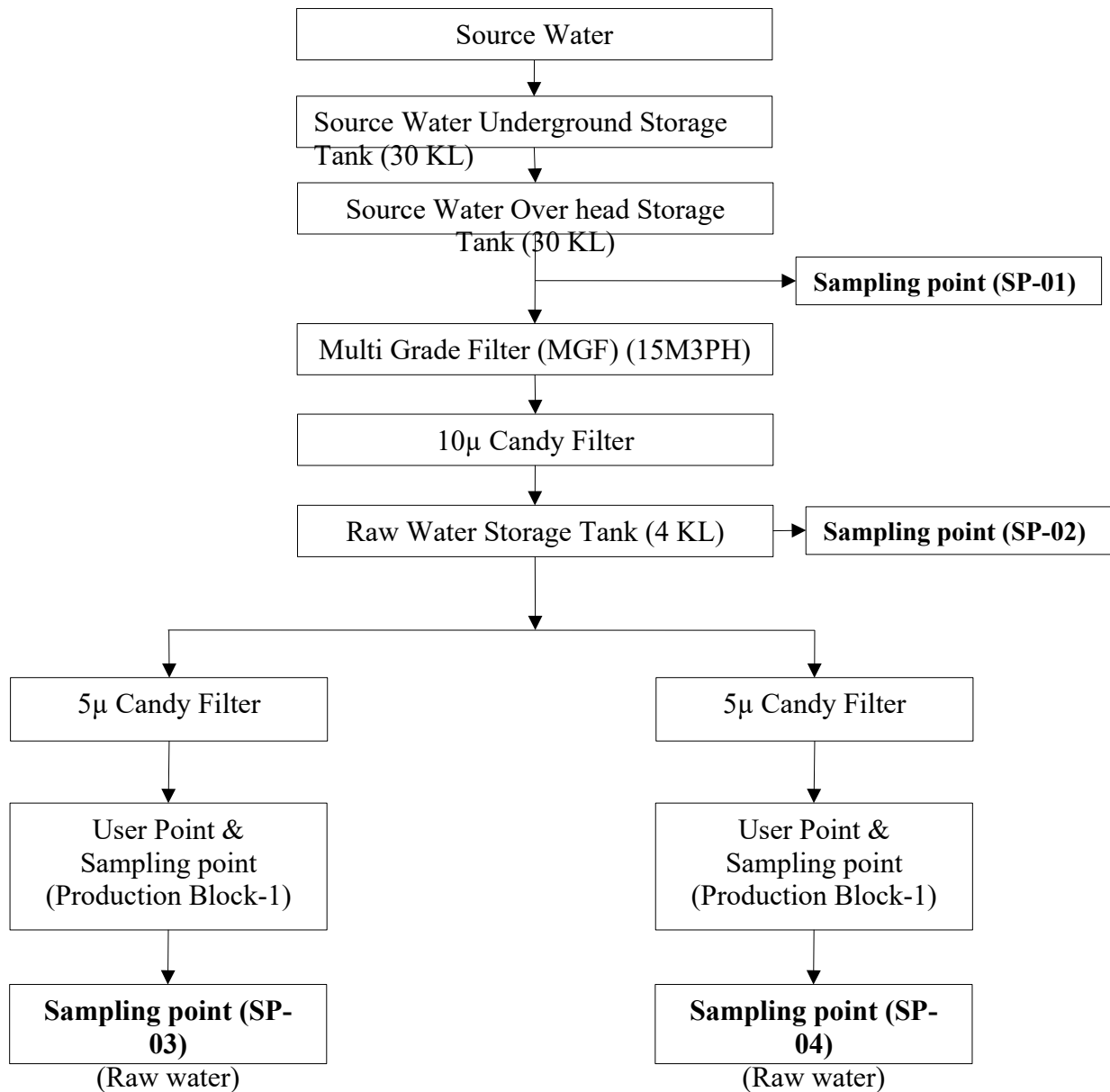
5.6 **Sampling procedure:**

- 5.6.1 Production department personnel shall raise analytical test requisition for water sampling and analysis purpose.
- 5.6.2 Quality control personnel shall collect the water sample from sampling point.
- 5.6.3 After receiving ATR QC personnel shall take a clean and dried 500 ml sample bottles.
- 5.6.4 Open the sampling point valve and drain the water for 30 to 60 seconds minutes.
- 5.6.5 Hold the bottle under the nipple and collect the minimum of 30 ml of sample for rinsing of glass sample bottle.
- 5.6.6 Rinse the bottle minimum of three times and collect the sample without leaving any headspace. Close the sample point valve.
- 5.6.7 Enter the details on the sampled label and affix on sampling bottle.
- 5.6.8 Analysis sample as per Specification and MOA.

5.7 **Maintenance and sampling procedure for Water as follows:**

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5.8 10µ & 5µ Candy filter: (Frequency for replacing filter cartridge: Quarterly).

5.8.1 Open the Candy filter and replacing the old cartridge with new cartridge for every three month.

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5.8.2 Assemble the housing along with the cartridge.

5.8.3 Record the replacement of the cartridge.

5.9 SCHEDULE:

5.9.1 Source water : Collect daily one sample from water sampling point (SP-01).

5.9.2 Raw water: Daily once after validation.

First day	User Point & Sampling points (SP-03)
Second day	User Point & Sampling points (SP-04)
Third day	User Point & Sampling points (SP-03)
Fourth day	User Point & Sampling points (SP-04)
And so on...	

5.9.3 Replacing filter cartridge: Quarterly.

5.9.4 Chemical analysis: Daily.

5.9.5 Microbial analysis: Once in month.

6.0 Formats / annexure(S):

6.1 Replacement of filters used in water system : ED020-FM059

6.2 Operating of water system : ED020-FM060

7.0 Change History:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.01.2018	New SOP	---

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