1. **PURPOSE:**

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

1. **SCOPE:**

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

1. **RESPONSIBILITY:**
   1. It is the responsibility of the Engineering department personnel to operate and maintain as per procedure described in this SOP.
   2. It is responsibility of production department raise ATR to QC.
   3. It is the responsibility of quality control department sampling and analyze the water sample.
2. **Definitions:** nil
3. **PROCEDURE :**
   1. This Source water shall be collected from underground storage tank.
   2. The treated raw water shall be collected in the HDPE tank.
   3. **Operating procedure**:
      1. Turn on Multi grade filter.
      2. Switch on the Raw water pump.
      3. Source water passes through the Multi grade filter (MGF) which contain 10µ Candy filter and collect the water in HDPE storage tank
      4. Whenever required, ensure the Raw water level.
      5. Two distribution points are present in plant and each distribution point connected with candy filter (5µ) followed by flow meter.
   4. **Multi Grade Filter:**
      1. Multi grade filter remove the extraneous matter present in the water.
      2. If Multi grade filter become clogged after a period of usage, then back washed to remove clog.
      3. Switch on Multi grade backwash mode daily once as follows.
      4. Put multi-port valve on back wash mode, Open source water inlet valve.
      5. Start the Source water pump.
      6. Pass the water for 10-15 minutes through the multi grade filter and allow to drain.
      7. After that, stop the source water pump and close the source water inlet valve.
   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

* 1. **Sampling procedure:**
     1. Production department personnel shall raise analytical test requisition for water sampling and analysis purpose.
     2. Quality control personnel shall collect the water sample from sampling point.
     3. After receiving ATR QC personnel shall take a clean and dried 500 ml sample bottles.
     4. Open the sampling point valve and drain the water for 30 to 60 seconds minutes.
     5. Hold the bottle under the nipple and collect the minimum of 30 ml of sample for rinsing of glass sample bottle.
     6. Rinse the bottle minimum of three times and collect the sample without leaving any headspace. Close the sample point valve.
     7. Enter the details on the sampled label and affix on sampling bottle.
     8. Analysis sample as per Specification and MOA.
  2. **Maintenance and sampling procedure for Water as follows**:

Source Water

Source Water Underground Storage Tank (30 KL)

Multi Grade Filter (MGF) (15M3PH)

10µ Candy Filter

Raw Water Storage Tank (4 KL)

User Point &

Sampling point

(Production Block-1)

5µ Candy Filter

***Sampling point (SP-03)***

(Raw water)

Source Water Over head Storage Tank (30 KL)

***Sampling point (SP-01)***

***Sampling point (SP-02)***

User Point &

Sampling point

(Production Block-1)

5µ Candy Filter

***Sampling point (SP-04)***

(Raw water)

* 1. **10µ & 5µ Candy filter: (Frequency for replacing filter cartridge: Quarterly).**
     1. Open the Candy filter and replacing the old cartridge with new cartridge for every three month.
     2. Assemble the housing along with the cartridge.
     3. Record the replacement of the cartridge.
  2. **SCHEDULE:**
     1. Source water : Collect daily one sample from water sampling point (SP-01).
     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… | |

* + 1. Replacing filter cartridge: Quarterly.
    2. Chemical analysis: Daily.
    3. Microbial analysis: Once in month.

1. **Formats / annexure(S):** 
   1. Replacement of filters used in water system : ED020-FM059
   2. Operating of water system : ED020-FM060
2. **Change History:**

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