



## Title: Water Sampling Procedure

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|------------------------|--|-----------------------|--------|
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### 1.0 PURPOSE

To lay down the procedure for sampling of water for Microbiological and Chemical analysis.

### 2.0 SCOPE

This is applicable to quality control department.

### 3.0 RESPONSIBILITY

Microbiology personnel

### 4.0 PROCEDURE

#### 4.1 Sampling of water for Microbiological analysis

4.1.1 Before sampling ensure that the sampling kit is available as per the details mentioned in Annexure – III.

4.1.2 Refer Annexure IV for the sampling points for a particular day.

Note: The schedule shall be prepared before start of particular month.

4.1.3 Samples for microbiological evaluation should be collected in Pre-sterilized screw cap glass bottles.

4.1.4 For sampling of Treated Raw water (May contain chlorine), add 0.1 ml of 5 % Sodium Thiosulphate solution in the bottles before sterilization.

Note: Before sampling, the aluminium foil covering the sampling point should be removed.

4.1.5 Wear the sterile hand gloves and remove the cap of the bottle just prior collecting the sample.

4.1.6 The "sample contact area of cap" should not come in contact with any surface, including the fingers or hands of the individual collecting the sample.

4.1.7 The cap may be set on the top of a clean surface, topside against the surface.

4.1.8 Open the sampling/user point valve until there is a steady stream of water.

4.1.9 Drain for approximately 1 minute, collect water in sampling bottle.

4.1.10 Do not allow the 'bottle' or the 'water in the bottle' to come in contact with the valve.

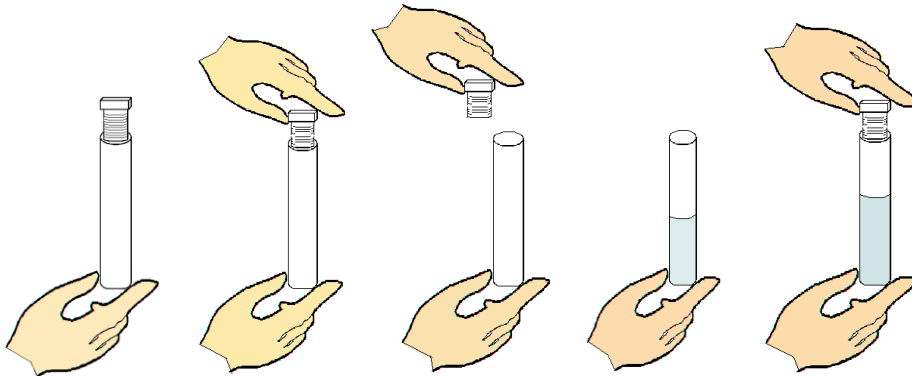
4.1.11 Fill the bottle without overflowing the bottle.



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- 4.1.12 Remove the bottle from the sample stream and place the cap on the bottle as quickly as possible.
- 4.1.13 Tighten the cap securely.
- 4.1.14 Close the valve.
- 4.1.15 Fill the information on the face of the bottle such as location of sampling, date of sampling and signature.
- 4.1.16 Collect all samples as per the Annexure-II and Proceed for analysis as per the SOP. If the samples are not taken immediately for analysis store it at refrigerator (2-8°C).
- 4.1.17 Ensure that analysis is initiated within 24 hrs after sampling.



**4.2 Sampling of water for Bacterial Endotoxin Testing**

- 4.2.1 Samples for bacterial endotoxin test should be collected in depyrogenated vials covered with aluminum foil.
- 4.2.2 Remove the aluminum foil from the vial immediately prior to collecting the sample.
- 4.2.3 The "sample contact area of aluminium foil" should not come in contact with any surface, including the fingers or hands of the individual collecting the sample.
- 4.2.4 The foil may be set on the top of a clean surface, topside against the surface.
- 4.2.5 Open the sampling/user point valve until there is a steady stream of water.
- 4.2.6 Drain for approximately 1 minute, collect water in sampling vial.
- 4.2.7 Do not allow the 'vial' or the 'water in the vial' to come in contact with the valve.



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- 4.2.8 Fill the vial, without overflowing the vial.
- 4.2.9 Remove the vial from the sample stream and place the aluminium foil on the vial as quickly as possible.
- 4.2.10 Cover the vial with aluminium foil after sampling.
- 4.2.11 Close the valve.
- 4.2.12 Fill the information on the face of the bottle such as location of sampling, date of sampling and signature.
- 4.2.13 Collect all samples as per the Annexure-II and Proceed for analysis as per the SOP. If the samples are not taken immediately for analysis store it at refrigerator (2-8°C).
- 4.2.14 Ensure that analysis is initiated within 24 hrs after sampling.

**4.3 Sampling of water for Chemical analysis**

- 4.3.1 Samples for chemical analysis should be collected in a clean and dried bottle.
- 4.3.2 Remove the cap from the bottle just prior to collect the sample.
- 4.3.3 The sample side of the cap should not come in contact with any surface, including the finger or hands of the individual obtaining the sample.
- 4.3.4 The cap may be kept on the top of a clean surface, topside against the surface.
- 4.3.5 Open the sampling/user point valve until there is a steady stream of water.
- 4.3.6 Drain for approximately 1 minute, Collect water in sampling bottle.
- 4.3.7 Rinse the bottle with the water to be sampled at least three times.
- 4.3.8 Do not allow the bottle or the water in the bottle to come in contact with the valve.
- 4.3.9 Fill the bottle and remove the bottle from the sample stream and place the cap on the bottle as quickly as possible and ensure that no air bubble is entrapped.
- 4.3.10 For TOC analysis collect the sample in the separate vials/bottles. Collect the sample by over flowing the vials and close with the lid/cap immediately.
- 4.3.11 Close the valve.



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4.3.12 Fill the information on the face of the bottle such as location of sampling, date of sampling and signature.

4.3.13 Collect all samples as per the Annexure-II and Proceed for analysis as per the SOP. If the samples are not taken immediately for analysis store it at refrigerator (2-8°C).

4.3.14 Ensure that the analysis is in any case is initiated within 24 hrs after sampling.

**4.4 Shipment**

4.4.1 If a contract laboratory is utilized, samples shall be sent by express service to arrive at the contract laboratory.

4.4.2 Sample container transfer "boxes" should include provisions for maintaining the sample temperature below 25°C at any time.

4.4.3 Samples should not be frozen or cooled to a temperature < 2°C.

**4.5 Numbering of test data sheet.**

Where,

4.5.1 Number the test data sheet according to YXXNNNN

Y = Last digit of current year.

XX = Code number of water type

such as (Raw water-RW, Soft water-SW, Potable water -DW, Drinking water-DR, RO water-RO, Purified water-PW, Water for injection-WF, Pure steam-PS).

NNNN = Serial No. starting from 0001.

4.5.2 Allot the test data sheet number in Annexure-I in remark column.

**4.6 Document numbering of test data sheet**

Where,

4.6.1 Document numbering of test data sheet is as follow TDS/XX/00N

TDS = Test data sheet

XX = Code number of water type

such as (Raw water-RW, Soft water-SW, Potable water-DW, Drinking Water-DR, RO water-RO, Purified water-PW, Water for injection-WF, Pure steam-PS).

NNN = Serial No. starting from 001.



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### 5.0 ABBREVIATIONS AND DEFINITIONS

|      |                              |
|------|------------------------------|
| SOP  | Standard Operating Procedure |
| QCM  | Quality Control Microbiology |
| QAD  | Quality Assurance Department |
| REV. | Revision                     |
| No.  | Number                       |
| %    | Percent                      |
| mL   | Milli litre                  |
| °C   | Degree Centigrade            |
| hrs  | Hours                        |
| TOC  | Total Organic Carbon         |
| RW   | Raw Water                    |
| SW   | Soft Water                   |
| DW   | Potable water                |
| DR   | Drinking water               |
| PW   | Purified Water               |
| WF   | Water for Injection          |
| PS   | Pure steam                   |
| TDS  | Test Data Sheet              |

### 6.0 REFERENCE DOCUMENTS

SOP Procedure for analysis of Water

### 7.0 ANNEXURE / ATTACHMENTS

Annexure I: Form 1 –SAMPLING RECORD.

Annexure II: Form 2 – WATER SAMPLING MATRIX.

Annexure III: Form 3 – WATER SAMPLING REQUIREMENT LIST.

Annexure IV: Form 4 – MONTHLY WATER SAMPLING SCHEDULE

Annexure V: WATER SAMPLING LAYOUT



# PHARMA DEVILS

ENGINEERING DEPARTMENT

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## 8.0 REVISION LOG

| Revision Number | Effective Date | Reason for Revision |
|-----------------|----------------|---------------------|
|                 |                |                     |