



## PRODUCT MANUAL FOR WATER STILLS FOR PYROGEN-FREE DISTILLED WATER ACCORDING TO IS 3830: 1979

*This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.*

|    |                                                                                         |                                               |                                                                                                                      |
|----|-----------------------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 1. | <b>Product</b>                                                                          | :                                             | IS 3830: 1979                                                                                                        |
|    | <b>Title</b>                                                                            | :                                             | Water Stills for Pyrogen-Free Distilled Water                                                                        |
|    | <b>No. of Amendments</b>                                                                | :                                             | 3                                                                                                                    |
| 2. | <b>Sampling Guidelines:</b>                                                             |                                               |                                                                                                                      |
| a) | <b>Raw material</b>                                                                     | :                                             | i) As per Cl. 2 and Cl. 6.2 of IS 3830: 1979.<br>ii) Immersion type heaters shall be ISI marked as per IS 302-2-201. |
| b) | <b>Grouping guidelines</b>                                                              | :                                             | Please refer ANNEX – <a href="#">A</a>                                                                               |
| c) | <b>Sample Size</b>                                                                      | :                                             | 1 Number                                                                                                             |
| 3. | <b>List of Test Equipment</b>                                                           | :                                             | Please refer ANNEX – <a href="#">B</a>                                                                               |
| 4. | <b>Scheme of Inspection and Testing</b>                                                 | :                                             | Please refer ANNEX – <a href="#">C</a>                                                                               |
| 5. | <b>Possible tests in a day :</b>                                                        |                                               | Dimensional measurements (Cl. No. 2.1, 4.5.2, 5.1.2),<br>Shape and capacity( Cl. No. 3), Distillate output (Cl.3.2)  |
| 6. | <b>Scope of the Licence:</b>                                                            |                                               |                                                                                                                      |
|    | “Licence is granted to use Standard Mark as per IS 3830: 1979 with the following scope: |                                               |                                                                                                                      |
|    | Name of the product                                                                     | Water stills for pyrogen-free distilled water |                                                                                                                      |
|    | Type                                                                                    | Electric-heated or Steam-heated               |                                                                                                                      |
|    | Capacity                                                                                |                                               |                                                                                                                      |
|    | Distillate output (in litres/hour)                                                      |                                               |                                                                                                                      |

**ANNEX A**

**Grouping Guidelines**

1. For considering GoL/CSoL, the grouping based on Type shall be followed:

**Type:**

- a) Electric-heated
  - b) Steam-heated
2. One sample of the highest capacity and highest distillate output from each Type shall be drawn for testing.
  3. The Firm shall declare the varieties of water stills they intend to cover in the Licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.
  4. During the operation of the Licence, BO shall ensure that all the varieties covered in the Licence are tested in rotation to the extent possible

**ANNEX B****List of Test Equipment***Major test equipment required to test as per the Indian Standard*

| <b>Sr. No.</b> | <b>Test equipment</b>                                                                                                                                                      | <b>Tests used in with Clause Reference</b>              |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| 1.             | Thermometer<br>Glass Measuring Cylinder<br>Stop Watch                                                                                                                      | Capacity, Cl. 3.2 and as per Cl. 6.4                    |
| 2.             | Vernier Caliper                                                                                                                                                            | Dimensional measurements, as per Cl. 2.1, 4.5.2, 5.1.2. |
| 3.             | Hydrostatic Test Arrangement fitted with pressure gauge.                                                                                                                   | Steam Heating, as per Cl. 6.3                           |
| 4.             | Arrangement to determine quality of distillate as per Indian Pharmacopoeia requirements for 'water for injection'<br>Sterile, clean glass stoppered container<br>Autoclave | Quality of distillate, as per Cl. 9.1                   |

*The above list is indicative only and may not be treated as exhaustive.*

**ANNEX C**

**Scheme of Inspection and Testing**

**1. LABORATORY** - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

**1.1** The manufacturer shall prepare a calibration plan for the test equipments.

**2. TEST RECORDS** – The manufacturer shall maintain test records for the tests carried out to establish conformity.

**3. LABELLING AND MARKING** – As per the requirement of IS 3830:1979.

**3.1** Each still shall be accompanied by a manual which shall contain the formation as per Cl. 7.2 of IS 3830: 1979.

**4. CONTROL UNIT** – Water stills of each type and design manufactured in a day shall constitute a control unit.

**5. LEVELS OF CONTROL** - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

**5.1** All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

**6. REJECTIONS** – Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

**TABLE 1**

| (1)          |                       |             | (2)                                                                            | (3)               |                  |                                                                                                                                                                                                                                                                |
|--------------|-----------------------|-------------|--------------------------------------------------------------------------------|-------------------|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Test Details |                       |             | Test equipment requirement<br>R: required (or)<br>S: Sub-contracting permitted | Levels of Control |                  |                                                                                                                                                                                                                                                                |
| Cl.          | Requirement           | Test Method |                                                                                | No. of Sample     | Frequency        | Remarks                                                                                                                                                                                                                                                        |
|              |                       | Clause      | Reference                                                                      |                   |                  |                                                                                                                                                                                                                                                                |
| 2            | Materials             | 2.1, 2.2    | IS 3830                                                                        | S                 | One              | Each Consignment<br>Stainless steel sheets (IS 6911 or IS 6603) used to make components shall be ISI marked.<br>For gun metal (IS 306 or IS 318) used in making components, no further testing is required, if accompanied with test certificate or ISI marked |
| 3            | Shape and Capacity    | 3           | IS 3830                                                                        | R                 | One              | Each control unit<br>--<br>--<br>--<br>Requirements as per Cl. 6.5 and 6.6 are at the option of buyer.                                                                                                                                                         |
| 4            | Construction          | 4.1 to 4.5  | IS 3830                                                                        | R                 | One              |                                                                                                                                                                                                                                                                |
| 5            | Storage Tank          | 5           | IS 3830                                                                        | R                 | One              |                                                                                                                                                                                                                                                                |
| 6            | Performance           | 6.1 to 6.6  | IS 3830                                                                        | R                 | One              |                                                                                                                                                                                                                                                                |
| 7            | Marking               | 7           | IS 3830                                                                        | R                 | Each still<br>-- |                                                                                                                                                                                                                                                                |
| 9.1          | Quality of Distillate | --          | Indian Pharmacopoeia requirements for 'water for injection'                    | S                 | One              | Once in a Month<br>The test shall also be carried out, whenever there is any change in design/material of any of the component.                                                                                                                                |

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.