



उत्पाद मैनुअल
हेमोडायलिसिस और संबंधित चिकित्सा के लिए तरल पदार्थ की तैयारी और गुणवत्ता प्रबंधन
भाग 2 हेमोडायलिसिस अनुप्रयोगों और संबंधित चिकित्सा के लिए जल परिष्करण उपकरण
आईएस 17646 (भाग 2): 2021 / आईएसओ 23500-2: 2019 के अनुसार

PRODUCT MANUAL

PREPARATION AND QUALITY MANAGEMENT OF FLUIDS FOR HAEMODIALYSIS AND RELATED THERAPIES
PART 2 WATER TREATMENT EQUIPMENT FOR HAEMODIALYSIS APPLICATIONS AND RELATED THERAPIES
According to IS 17646 (Part 2): 2021 / ISO 23500-2: 2019

यह उत्पाद नियमावली सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसधारियों द्वारा विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना-1 के अंतर्गत प्रमाणन के संचालन में एकरूपता और पारदर्शिता सुनिश्चित करने के लिए संदर्भ सामग्री के रूप में उपयोग की जाएगी। बीआईएस प्रमाणन प्राप्त करने के इच्छुक भावी आवेदक भी इस दस्तावेज़ का उपयोग कर सकते हैं।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity 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.

1.	मानक संख्या / IS No.	:	IS 17646 (Part 2): 2021 / ISO 23500-2: 2019
	शीर्षक / Title	:	Preparation and Quality Management of Fluids for Haemodialysis and Related Therapies Part 2 Water Treatment Equipment for Haemodialysis Applications and Related Therapies
	संशोधनों की संख्या No. of amendments	:	Nil
2.	नमूनाकरण दिशानिर्देश / Sampling Guidelines		
a)	कच्चा माल Raw material	:	No specific requirement. <i>Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance.</i>
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	:	Please refer ANNEX – A
c)	नमूने का परिमाण Sample Quantity	:	- 01 machine - Water samples (5 litres + 5 litres)
d)	परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर Parameters to be Declared in Test Request	:	Same as the parameters given in scope of the licence under S. No. 6. <i>Note: Apart from the above, any other requirements/ parameters may also be declared as per the standard, as applicable.</i>
3.	परीक्षण उपकरण की सूची List of Test Equipment	:	Please refer ANNEX – B
4.	निरीक्षण एवं परीक्षण योजना Scheme of Inspection and Testing	:	Please refer ANNEX – C

5.	एक दिन में संभावित परीक्षण Possible tests in a day	:	Water treatment equipment requirements (Cl. 4.2) <i>Note: This section is for the guidance of BIS Certification Officers/ Technical Auditors of BIS Authorized Outside Surveillance Agencies (OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by the officer/ auditor.</i>
6.	लाइसेंस का दायरा / Scope of the Licence:		
“Licence is granted to use Standard Mark as per IS 17646 (Part 2): 2021 / ISO 23500-2: 2019 with the following scope:			
Name of the product		Water Treatment Equipment for Haemodialysis Applications and Related Therapies	
Model(s)			
Capacity		 lph	

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9, BAHADUR SHAH ZAFAR MARG, NEW DELHI-110002
www.bis.gov.in

ANNEX - A
Grouping Guidelines

1. Manufacturer shall submit declaration for each of the model of Water Treatment Equipment they intend to cover in the scope of licence. Further, the manufacturer shall also declare the essential accessories (if any) supplied along with the model.
2. For Grant of Licence/ Change in Scope of Licence, each Model of Water Treatment Equipment shall be tested.
3. During the operation of the Licence, BO shall ensure that all the model(s) covered in the Scope of the Licence are tested in rotation to the extent possible.

ANNEX- B
List of Test Equipments
(Indicative List, For Guidance Only)

Sl. No.	Clause Reference	Tests used	Test Equipment
1	4.1.2 / 5.1.3	Chemical contaminant requirements of dialysis water	Suitable equipment for chemical analysis by the specified/referenced method or any other appropriately validated and comparable analytical method.
2	4.1.4 / 5.1.2	Microbiology of dialysis water	Suitable microbiological testing equipment for membrane filtration, spread plate or pour plate technique, as applicable. Other appropriately validated and comparable methods may be used.
3	4.1.4 / 5.1.2	Endotoxins	Limulus amoebocyte lysate (LAL) assay or equipment for another validated test method.
4	4.2.1.1 / 5.2.1.1	Feed-water quality for water treatment equipment	Suitable test equipment corresponding to the parameter and test method selected. The tests are to be selected based on the specific features of the water treatment device.
5	4.2.1.2 / 5.2.1.2	Materials compatibility	Equipment/facilities appropriate to the biocompatibility tests identified from the risk analysis and testing rationale.
6	4.2.1.3 / 5.2.1.3	Regenerated or reconstituted devices	Suitable microbiological testing equipment for the applicable validated procedure; alternatively, equipment appropriate for the validated procedure for regenerated/reconstituted devices.
7	4.2.1.4 / 5.2.1.4	Disinfection protection	Suitable equipment for residual disinfectant determination, temperature measurement and ozone concentration measurement, as applicable, by the specified or appropriately validated comparable method.
8	4.2.2 / 5.2.2	Backflow prevention	Visual inspection.
9	4.2.3 / 5.2.3	Tempering valves	Visual inspection and review of manufacturer's specifications; suitable temperature measuring equipment, where required for verification.
10	4.2.4 / 5.2.4	Sediment filters	Visual inspection.
11	4.2.5 / 5.2.5	Cartridge filters	Visual inspection.
12	4.2.6 / 5.2.6	Softeners	Inspection of the equipment and applicable regeneration settings/arrangements.
13	4.2.7 / 5.2.7	Anion exchange resin tanks	Suitable equipment for determination of TOC or tannins, as applicable; inspection of salt usage and regeneration timer/settings.
14	4.2.8 / 5.2.8	Carbon media	DPD test kit or other suitable/validated test equipment for chlorine determination; online monitor or test strips may also be used as applicable. For questionable results, a suitable titrimetric or other validated method may be used.

Sl. No.	Clause Reference	Tests used	Test Equipment
15	4.2.9 / 5.2.9	Chemical injection systems	Inspection of the system and its operating/control arrangements. Suitable equipment for verification of dosing performance, where applicable.
16	4.2.10 / 5.2.10	Reverse osmosis	Temperature-compensated conductivity, resistivity or TDS measuring equipment, as applicable; equipment required for tests under 5.1.2 and 5.1.3.
17	4.2.11 / 5.2.11	Deionization	Resistivity measuring equipment with temperature compensation; visual inspection of required safety systems.
18	4.2.12 / 5.2.12	Endotoxin retentive filters	Equipment required for determining bacteria and endotoxin tests specified under 5.1.2.
19	4.2.13.1 / 5.2.13.1	Piping systems	Visual inspection; equipment required for the applicable microbiological and chemical tests under 5.1.2 and 5.1.3.
20	4.2.13.2 / 5.2.13.2	Storage tanks	Visual inspection.
21	4.2.13.3 / 5.2.13.3	Ultraviolet irradiators	Visual inspection.
22	4.2.13.4 / 5.2.13.4	Hot-water disinfection systems	Suitable calibrated temperature measuring/recording equipment capable of measuring the water temperature at the specified location and for the specified disinfection time; visual inspection of configuration.
23	4.2.13.5 / 5.2.13.5	Ozone disinfection systems	Online dissolved-ozone monitor or suitable test equipment based on an appropriate validated method; visual inspection of configuration.

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

ANNEX C

Scheme of Inspection and Testing

1. QUALITY ASSURANCE PLAN

- 1.1 It is expected that during operation of BIS licence manufacturers will implement a Quality Assurance Plan (QAP) i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.
- 1.2 The manufacturers shall define a Quality Assurance Plan (QAP) defining the control unit (i.e. lot/batch etc.), the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or sub-contracting/ sharing for each applicable test and submit the same to BIS Branch Office for information. The manufacturer shall comply with the QAP and maintain test records in accordance with para 2.1.
- 1.3 Recommended Levels of Control/ Control Unit:**
- 1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in [Table 1](#). Manufacturer has the discretion of declaring their own levels of control or accept the levels of control given in this document.
- 1.3.2 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan.
- 1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING

The manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard for which they may have in-house test facilities. However, there is no obligation to maintain in-house laboratory. Licensee may use alternative arrangements for tests of the production as per the declared QAP. Various alternatives are available for operation of BIS certification as given below and the relevant guidelines for availing such relaxations by the manufacturers, as amended from time to time, are to be referred:

- i) Shared testing resources like common facility,
- ii) Cluster based testing facility,
- iii) Sub-contracting to outside laboratories which may either be:
 - a) BIS recognized/ empanelled laboratories, or
 - b) Any accredited laboratory as per ISO/IEC 17025

2.1 Test Records- The manufacturers shall maintain test records for the tests carried out (either in-house or at a sub-contracted or at shared test facility) to establish conformity of the product to the Standard for operation of licence. For the tests being subcontracted or conducted at a shared test facility, test results issued by the laboratories or test facilities, shall be made available for inspection by BIS.

2.1.1 Technical File- Licensee shall maintain a Technical File for each model being manufactured by them. The Technical file shall be submitted to BIS at the time of Grant of Licence/ Inclusion/ Surveillance.

2.1.1.1 The Technical File shall be maintained till the End of Life of the model.

- 2.1.1.2 Licensee shall declare the frequency for periodic review in Technical file to BIS and record of review to be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licensee shall inform the same to BIS at the earliest and provide the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.
- 2.1.1.3 For changes in the product which shall affect the Scope of the Licence, the modified product shall be treated as a different model and separate Technical File shall be maintained for the same.
- 2.1.1.4 The technical file shall consist of the following documents:
- 2.1.1.4.1 A general description of the product;
 - 2.1.1.4.2 Product Manual and/ or Instructions for use;
 - 2.1.1.4.3 Instructions for repair/ service for the product/ components, if required;
 - 2.1.1.4.4 Frequency of periodic repair/ service for the product/ components, if required;
 - 2.1.1.4.5 Conceptual product design and manufacturing drawings and, where appropriate, list of components, electrical circuit design, etc. with descriptions and explanations needed for the understanding of these drawings;
 - 2.1.1.4.6 A list of the all Indian/ International standards applied in full or in part during the conformity assessment process with copy of test certificate/ test report;
 - 2.1.1.4.7 Test reports/ Test Certificates and Risk Assessment File for the product and/ or components as per relevant Clauses of the Indian Standard;
 - 2.1.1.4.8 Copies of Conformity Assessment documentation for critical product components;
 - 2.1.1.4.9 Copy of BIS licences for the product/ components, wherever applicable;
 - 2.1.1.4.10 A copy of the Declaration of Conformity for other International Standards;
 - 2.1.1.4.11 Other documents, if found necessary by the manufacturer and/ or by BIS may also be a part of the Technical File

3. LABELLING

The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each Water Treatment Equipment provided always that the Water Treatment Equipments so marked conforms to each requirement of the specification.

3.1 Labelling shall be done as per Cl. 6 of IS 17646 (Part 2): 2021/ ISO 23500-2: 2019.

3.2 **Additional Marking requirements:** The Water Treatment Equipment shall also be marked with the following additional requirement on the product:

- a) "For BIS certification details please visit www.bis.gov.in"

4. REJECTION

The production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. 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

(Recommended Levels of Control by BIS- for Guidance Only)

(1)				(2)		
Test Details				Levels of Control		
Cl.	Requirement	Test Method		No. of Sample	Frequency	Remarks
		Clause	Reference			
4	Requirements					
4.1	Dialysis water quality requirements					
4.1.2	Chemical contaminant requirements	5.1.3	IS 17646 (Part 2)	01	Once in a month	
		5.3	IS 17646 (Part 3)			
4.1.4	Microbiology of dialysis water	5.1.2	IS 17646 (Part 2)	01	Once in a month	
		5.1, 5.2	IS 17646 (Part 3)			
4.2	Water treatment equipment requirements					
4.2.1	General	5.2.1	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.1.1	Water treatment system	5.2.1.1	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.1.2	Materials compatibility	5.2.1.2	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.1.3	Regenerated or reconstituted devices	5.2.1.3	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.1.4	Disinfection protection	5.2.1.4	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.2	Backflow prevention device	5.2.2	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.3	Tempering valves	5.2.3	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.4	Sediment filters	5.2.4	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.5	Cartridge filters	5.2.5	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.6	Softeners	5.2.6	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.7	Anion exchange resin tank	5.2.7	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.8	Carbon media	5.2.8	IS 17646 (Part 2)	Each Water Treatment Equipment		
			IEC 60601-1-8			
4.2.9	Chemical injection systems	5.2.9	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.10	Reverse osmosis	5.2.10	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.11	Deionization	5.2.11	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.12	Bacteria and endotoxin retentive filters	5.2.12	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.13	Storage and distribution of dialysis water	5.2.13	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.13.1	Piping systems	5.2.13.1	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.13.2	Storage tanks	5.2.13.2	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.13.3	Ultraviolet irradiators	5.2.13.3	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.13.4	Hot water disinfection systems	5.2.13.4	IS 17646 (Part 2)	Each Water Treatment Equipment		
4.2.13.5	Ozone disinfection systems	5.2.13.5	IS 17646 (Part 2)	Each Water Treatment Equipment		
6	Labelling					
6.1	General	6.1	IS 17646 (Part 2)	Each Water Treatment Equipment		
6.2	Device markings	6.2	IS 17646 (Part 2)	Each Water Treatment Equipment		
6.3	Product literature	6.3	IS 17646 (Part 2)	Each Water Treatment Equipment		