भारतीय मानक ब्यरो

BUREAU OF INDIAN STANDARDS

अठारहवीं बैठक- चिकित्सा प्रयोगशाला उपकरण अनुभागीय समिति, एम.एच.डी-10

Eighteenth Meeting of Medical Laboratory Instruments Sectional Committee, MHD-10

कार्यसूची | AGENDA

Date	07 Aug 2023, Monday
Time	11:00 AM
Venue	**Virtual (Webex)** Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m5997b981e1e0604851238e005aa8233d Meeting id: 2518 430 2220 Password: Mhd10@18
Chairman	**Dr. Sudip Kumar Datta** Additional Professor and Head, Department of Laboratory Medicine, AIIMS, New Delhi
Member Secretary	Mr. Pawan Kumar Scientist B/Assistant Director, Medical Equipment and Hospital Planning Department Bureau of Indian Standards mhd10@bis.gov.in; mhd@bis.gov.in

ITEM 0 WELCOME AND OPENING REMARKS

0.1 Welcome Address by Head (MHD)
0.2 Opening Remarks by Chairperson

Agenda for 18th meeting of the Medical Laboratory Instruments Sectional Committee (MHD 10)
(*For BIS use only*)

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING.

The minutes of the last (Seventeenth) meeting of the Medical Laboratory Instruments Sectional Committee, held on 29 May 2023 via Webex VC and duly approved by the Chairman, were circulated to all the members on 19 June 2023. No comments were received regarding the accuracy of recording of the decisions taken in the meeting.

The committee may formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF COMMITTEE

2.1 The scope and present composition of the Medical Laboratory Instruments Sectional Committee, MHD 10, is given in ANNEX 1.

2.2 Members are also requested to provide their latest details like e-mail ids, phone no., official address etc. to the BIS secretariat to enable correspondence and send documents/Agenda/Minutes etc. through e-mail.

2.3 The committee may also recommend organizations/manufacturers which may be co-opted into the committee in order to strengthen the work of formulation of Indian National Standards

2.4 Review of composition:

Organizations recommended for withdrawal:

Sl. No.	Organization	Attendance out of last 3 meetings
1	Indian Council of Medical Research, New Delhi	0/3
2	Post Graduate Institute of Medical Education and Research, Chandigarh	0/3

Committee may consider.

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

There are no draft Indian Standards/amendments pending for approval for finalization.

ITEM 4 DRAFT STANDARDS / AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

There are no draft Indian Standards/amendments pending for approval for wide circulation.

ITEM 5 DRAFTS UNDER PREPARIATION

Following Indian standards are to be revised

Sl No.	IS no.	Title
1	IS 3741 (Part 1) : 1990	Medical instruments sedimentation tubes - Specification Part 1 westergren tube Second Revision
2	IS 3741 (Part 2) : 1990	Medical glass instruments - Sedimentation tubes - Specification Part 2 wintrobe tube Second Revision
3	IS 3742 : 1990	Medical glass instruments - Pipettes dilution for haemocytometers specification Second Revision
4	IS 4529 : 1968	Specification for glass tubes for medical thermometers
5	IS 10615 : 1983	Needle Holder Bozemanns Pattern
6	IS 12622 : 1989	Medical thermometers for hypothermia subnormal range - Specification

The committee may deliberate and decide

ITEM 6 COMMENTS ON PUBLISHED STANDARD

The following Indian standards were circulated within the committee for perusal, comments have been received on the following Indian standard and are:

IS 7039:1973 Specifications for tube culture with screw cap

Comments attached at **Annex 2**

IS 7183: 1973 Specification for flask culture haffkine

Comments attached at **Annex 3**

IS 4381 : 1967 Specification for pathological microscope

Comments attached at **Annex 4**

BIS has two Indian Standards on Evacuated Tubes for Blood Sample Collection. In the last meeting of Medical laboratory instruments (MHD-10), it was decided to conduct a comparative study of following standards:

a) IS 10916: 1984 ‘Specification for evacuated tubes for blood specimen collection (vacutainers)’

b) IS 10867: 2018 (ISO 6710: 2017) Single-Use Containers for Human Venous Blood Specimen Collection (First Revision)

Comments has been received from Shri P. K. Sharma, Hindustan Syringes and Medical Devices Limited, Faridabad attached in **Annex 5**. A panel meeting is being planned to discuss further course of action in this regard.

The penal composition is as follows:

Sl. No.	**Name and organization**
1)	Shri Sudhakar Mairpadi, *Becton Dickinson India Private Limited, Gurugram*
2)	Shri P. K. Sharma, *Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad*
3)	Dr Chandrashekhar Raut, *Dr D. Y. Patil Medical College, Hospital and Research Centre, Pune*
4)	Dr. Saswati Das, *Dr Ram Manohar Lohia Hospital, New Delhi*
5)	Smt. Sushmita Roy Chowdhury, *Kalam Institute of Health Technology, Vishakhapatnam*

ITEM 7 NEW SUBJECTS

7.1 The committee may deliberate on the emerging fields in the area under its scope and decide formulation of Indian Standards on the same. The committee may define thrust area which should take into consideration the standards development required in the given context keeping in view the social, environmental, and economic consideration.

The committee may deliberate and decide.

ITEM 8 PROGRAM OF WORK

The present programme of work (POW) of the Medical Laboratory Instruments Sectional committee is given in **ANNEX 6.**

ITEM 9 DATE AND PLACE OF NEXT MEETING

As per the approved meeting calendar the next meeting will tentatively be held on November 6, 2023, Thursday.

ITEM 10 ANY OTHER BUSINESS

Committee may suggest.

Agenda for 18th meeting of the Medical Laboratory Instruments Sectional Committee (MHD 10)
(*For BIS use only*)

Annex 1

Scope: To formulate Indian Standards for medical laboratory instruments and medical laboratory equipments and glasswares in all in-vitro diagonistics medical laboratories including clinical-pathology, hematology, histopathology, cytopathology, flow-cytometery, biochemistry, microbiology and molecular biology

COMPOSITION OF SECTIONAL COMMITTEE

S.No.	Organization	Member Name	Role
1	All India Institute of Medical Sciences, New Delhi	Dr. Sudip Datta	Chairperson
2	All India Institute of Medical Sciences, New Delhi	Dr Tushar Sehgal	Alternate Member
3	Association of Indian Medical Device Industry, New Delhi	Shri Rakesh Jain	Principal Member
4	Association of Indian Medical Device Industry, New Delhi	Shri Shailesh Patel	Alternate Member
5	Becton Dickinson India Private Limited, Gurugram	Shri Neeraj Sharma	Alternate Member
6	Becton Dickinson India Private Limited, Gurugram	Mr. Sudhakar Mairpady	Principal Member
7	Bharati Vidyapeeth Medical College, Pune	Col Mahadevan Kumar	Alternate Member
8	Borosil Glass Works Limited, Mumbai	Shri Satish Chitriv	Alternate Member
9	Borosil Glass Works Limited, Mumbai	Shri Jeevan Dogra	Principal Member
10	Borosil Technologies Limited, Pune	Shri Mahesh Surve	Alternate Member
11	Borosil Technologies Limited, Pune	Shri Sreejith Kumar PS	Principal Member
12	Boston Scientific India Private Limited, Gurugram	Shri Prashanth Prabhakar	Principal Member
13	Boston Scientific India Private Limited, Gurugram	Shri Dev Chopra	Alternate Member
14	CSIR - National Physical Laboratory, New Delhi	Dr G. Sumana	Principal Member
15	CSIR - National Physical Laboratory, New Delhi	Dr Rajesh	Alternate Member
16	CSIR - National Physical Laboratory, New Delhi	Dr. Tuhin Kumar Mandal	Young Professional
17	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr. Neelesh Kumar	Principal Member
18	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr Sanjeev Soni	Alternate Member
19	Central Drugs Standard Control Organization, New Delhi	Shri Sella Senthil	Alternate Member

S.No.	Organization	Member Name	Role
20	Directorate General of Health Services, New Delhi	Dr. Naresh Panchal	Principal Member
21	Dr D. Y. Patil Medical College, Hospital and Research Centre, Pune	DR CHANDRASHEKHAR G RAUT	Principal Member
22	Dr Ram Manohar Lohia Hospital, New Delhi	Prof. Dr. Arvind Ahuja	Principal Member
23	Dr Ram Manohar Lohia Hospital, New Delhi	Dr. Saswati Das	Alternate Member
24	Dr Ram Manohar Lohia Hospital, New Delhi	Dr. Arvind Kumar Achra	Young Professional
25	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Shri Praveen Kumar Sharma	Principal Member
26	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Shri Upinder Vishen	Alternate Member
27	Holy Family Hospital, New Delhi	Dr. Aditi	Principal Member
28	Holy Family Hospital, New Delhi	Shri Neil Aldrin Milton	Alternate Member
29	ICAR - Indian Veterinary Research Institute, Izzatnagar	Dr Sameer Srivastava	Alternate Member
30	ICAR - Indian Veterinary Research Institute, Izzatnagar	Dr Amar Pal	Principal Member
31	ICAR - National Institute of Cancer Prevention Research, Noida	Dr Sanjay Gupta	Alternate Member
32	ICAR - National Institute of Cancer Prevention Research, Noida	Dr Ruchika Gupta	Principal Member
33	ICMR - National Institute of Immunohaematology, Mumbai	Dr. Bipin Prakash Kulkarni	Principal Member
34	ICMR - National Institute of Immunohaematology, Mumbai	Dr. Anindita Banerjee	Alternate Member
35	ICMR - National Institute of Immunohaematology, Mumbai	Dr. Umair Bargir	Young Professional
36	Indian Council of Medical Research, New Delhi	Dr B. C. Das	Principal Member
37	Indian Council of Medical Research, New Delhi	Dr Sanjay Gupta	Alternate Member
38	Kalam Institute of Health Technology, Vishakhapatnam	Shri Dilip Kumar Chekuri	Alternate Member
39	Kalam Institute of Health Technology, Vishakhapatnam	Smt. Sushmita Roy Chowdhury	Alternate Member
40	Kalam Institute of Health Technology, Vishakhapatnam	Smt. Priyadarshini A	Young Professional
41	Magnus Opto Systems India Private Limited, New Delhi	Shri Harmeet Singh Ahuja	Principal Member
42	Magnus Opto Systems India Private Limited, New Delhi	Shri Deepak Yadav	Alternate Member
43	Maulana Azad Medical College, New Delhi	DR ROHIT CHAWLA	Alternate Member
44	Maulana Azad Medical College, New Delhi	Dr. Sonal Saxena	Principal Member
45	Ministry of Consumer Affairs, Food and Public Distribution, Department of Consumer Affairs, New Delhi	SHRI RAJ KUMAR	Alternate Member
46	Ministry of Consumer Affairs, Food and Public Distribution, Department of Consumer Affairs, New Delhi	Shri B N Dixit	Principal Member

47	Ministry of Environment Forest and Climate Change, New Delhi	Dr Satyendra Kumar	Principal Member
48	Ministry of Environment Forest and Climate Change, New Delhi	Shri N. Subrahmanyam	Alternate Member
49	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Gayathri S	Principal Member
50	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Shri Ashok Kumar	Alternate Member
51	National Centre for Disease Control, New Delhi	Smt. Dr. MONIL SINGHAI	Principal Member
52	National Centre for Disease Control, New Delhi	Dr. Shubha Garg	Alternate Member
53	National Institute of Pathology, New Delhi	Dr. Sandeep Agrawal	Principal Member
54	National Institute of Pathology, New Delhi	Dr. Garima Jain	Alternate Member
55	Post Graduate Institute of Medical Education and Research, Chandigarh	Shri PROF. VIVEK LAL	Alternate Member
56	Post Graduate Institute of Medical Education and Research, Chandigarh	Shri Prof. Bishan Dass Radotra	Principal Member
57	Schott Glass India Private Limited, Pune	Shri Anand Bakshi	Principal Member
58	Schott Glass India Private Limited, Pune	Smt. Sugna Verma	Alternate Member
59	Shriram Institute for Industrial Research, Delhi	Manish Rawat	Principal Member
60	Shriram Institute for Industrial Research, Delhi	Surabhi Gupta	Alternate Member
61	Terumo Penpol Private Limited, Thiruvananthapuram	Shri B. Harikrishanan	Alternate Member
62	Terumo Penpol Private Limited, Thiruvananthapuram	Shri Manoj A.	Principal Member
63	Thermo Fisher Scientific India Private Limited, Mumbai	Shri Vijay Kumar	Principal Member
64	Thermo Fisher Scientific India Private Limited, Mumbai	Shri Manish Shanghai	Alternate Member
65	Thermo Fisher Scientific India Private Limited, Mumbai	Shri Ghosh Debjyoti	Young Professional
66	University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi	Dr. Nadeem Tanveer	Principal Member
67	University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi	Dr. Preeti Dewakar	Alternate Member
68	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Rajni Dawar	Alternate Member
69	Voluntary Organisation in Interest of Consumer Education (VOICE), New Delhi	Shri M. A. U. Khan	Principal Member
70	Voluntary Organisation in Interest of Consumer Education (VOICE), New Delhi	Shri B. K. Mukhopadhyay	Alternate Member

Annax 2

DOC NO: IS 7039 - 1973
TITLE: Specification for Tube, Culture, Screw Cap
LAST DATE OF COMMENTS:
NAME OF THE COMMENTATOR/ORGANIZATION: Satish Chitriv (BOROSIL LIMTED)

Sl. No. [1]	Clause/Sub-clause/ para/table/fig. No. commented [2]	Type of Comments (General(*ge*)/ Editorial(*ed*)/ Technical(*te*)) [3]	Justification* [4]	Proposed change* [5]
1	1	Technical	Customers are using 50ml, 60ml & 150ml Culture tubes also for biology and related sciences for handling and culturing all kinds of live organisms, such as molds, bacteria, seedlings, plant cuttings, etc.	New addition of 50 ml, 60 ml & 150 ml capacity
2	3.2	Technical	Now a days the customers are demanding for PP cap with PTFE / Silicon wad	The MOC of cap can be PP (Food grade) also as required by the purchaser.
3	3.3	Technical	Now a days the customers are demanding for PP cap with PTFE / Silicon wad	The MOC of wad can be PTFE or silicon (Food grade) also as required by the purchaser.
4	Fig. 1	Technical	Due to addition of PP as one more option for MOC of cap	Cap can be bakelite of PP as per requirement.
5	Nominal capacity / Thread Size	Technical	Due to addition of new capacities.	**Nominal Capacity – Threads** 5 ml – GL 14 10 ml – GL 16 15 ml – GL 18 30 ml – GL 20 50 ml – GL 20 60 ml – GL 20 150 ml – GL 36

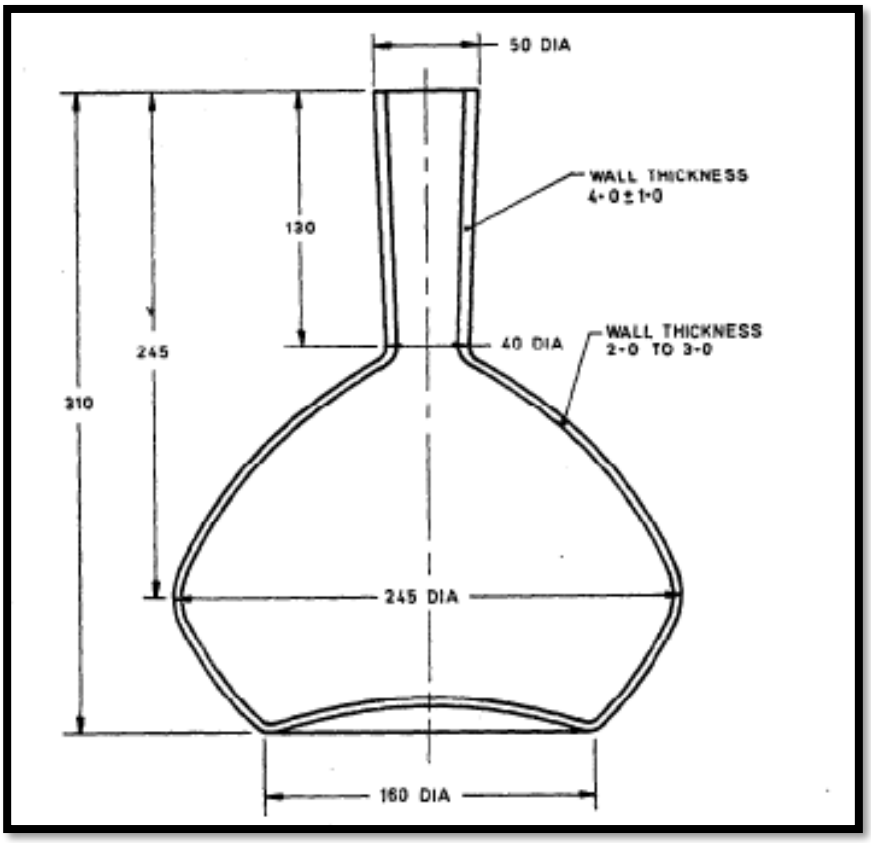
Annex 3

DOC NO: IS 7183 - 1973
TITLE: Specification for Flask, Culture, Haffkine
LAST DATE OF COMMENTS:
NAME OF THE COMMENTATOR/ORGANIZATION: Satish Chitriv (BOROSIL LIMTED)

Sl. No. [1]	Clause/Sub-clause/ para/table/fig. No. commented [2]	Type of Comments (General(*ge*)/ Editorial(*ed*)/ Technical(*te*)) [3]	Justification* [4]	Proposed change* [5]
1	1	Technical	Customers are using 3L Haffkine flasks too for preparation of culture in nutrient media and Borosil & other laboratory glassware manufacturer in India	New addition of 3L capacity
2	2	Technical	3.3 Borosilicate glass is generally used for all type of laboratory glassware manufacturing by all laboratory glassware manufacturer in India	Material should be 3.3 Borosilicate glass instead of neutral glass
3	3	Technical	Due to addition of 3L capacity	Fig. 1 to be replaced and table for dimensions of 3L & 4L capacity to be added
4	4.6	Technical	Due to addition of 3L capacity	Need to add capacity of 3L flask upto the neck like 4L capacity in the existing standard.
5	5.3	Technical	It is a standard and recommended autoclave temperature.	Autoclaving temperature at 121 °C to be added as a process parameter

Table 1

Capacity	Total Height (H)	Body Diameter (D)	Bae Diameter (D1)	Neck Height (h)	Neck OD at top (D2)	Neck OD at bottom (D)	Neck Wall thickness (t)	Body wall thickness (t1)
3 L	280	245	Approx.160	125	50	40	4 ± 1	2.0 to 3.0
4 L	310	245	Approx.160	130	50	40	4 ± 1	2.0 to 3.0


50 DIA
WALL THICKNESS
4·0 ± 1·0
130
245
310
40 DIA
WALL THICKNESS
2·0 TO 3·0
245 DIA
160 DIA

Annex 4

DOC NO: IS 4381
TITLE : Specification of Pathological Microscope
LAST DATE OF COMMENTS: **28 May 2022**
NAME OF THE ORGANIZATION: **Magnus Opto Systems India Pvt. Ltd**.

Sl. No. [1]	Clause/Sub-clause/ para/table/fig. No. commented [2]	Commentator/ Organization/ Abbreviation [3]	Type of Comments (General/Editorial/ Technical) [4]	Justification [5]	Proposed change [6]
1	IS 3081,CL No 2.2 ,Table 1	Magnus	Technical	The value of External thread of objective (Male Thread) should be lower than internal thread of nosepiece (Female Thread)	Thread table should be exchanged with each other for external & internal thread.
2	IS 3081 , FIG 1	Magnus	General	Ocular outer diameter should not be fixed as it may be vary with field number of eyepiece	Ocular diameter 28h11 may be removed and kept open as it has no relevance.
3	IS 3081 , FIG 1	Magnus	General	Condenser receptacle & Condenser diameter should not be fixed i.e. 39.5 G7 & 39.5h6 respectively	Condenser receptacle & condenser diameter i.e. 39.5G7 &39.5h6 may be removed and kept open as it has no relevance.
4	IS 4381 CL No 1.1 (Scope)	Magnus	Technical	It is mentioned that it is for monocular only but it's a standard for pathological microscope , so it may be binocular and Trinocular too. We need to apply for IS 8275 separately for binocular	The reference should be revised for monocular,binocular & trinocular instead of only monocular
5	IS 4381 CL No 5.2	Magnus	Technical	The fine motion should be 0.2mm or 0.3 mm per revolution as per the design. In this category of microscope 0.1mm does not exist.	The reference may be removed and replaced as proposed.

Annex 5

Comparative Study of IS 10916-1984 {Specification for evacuated tubes for blood specimen collection (vacutainers)} & ISO 6710-2017 {Single- use containers for human venous blood specimen collection}

(Date: 24.07.23)

Clause		ISO 6710:2017	IS 10916:1984	Remark
1	**Scope**	This standard specified the requirement and test method for Evacuated and non-evacuated single use venous blood specimen containers. It does not specify requirement for blood collection needle, needle holder, blood culture receptacles or "arterial" blood gas collection device that can be used for venous blood.	**1.1** This standard specified the requirement for single use Evacuated Blood Specimen collection tube intended primarily for haematological, biochemical and serological use. **1.2** This standard cover the tube size having nominal capacity up to 20 ml.	In IS 10916 mentioned the tube capacity up to 20ml only. In ISO does not specify requirement for blood collection needle, needle holder.
2	**Normative reference**	The following document are referred to in the text in such a way that some or all of their content constitutes requirement of this document. For dated reference only the addition cited applies. For undated reference, the latest edition of the referenced documents applies.	----	
3	**Terms and definitions**	For the purpose of this document, the following terms and definition apply. ISO & IEC maintain terminological data base for use in standardization.	**2.0** For the purpose of this standard following definitions shall apply.	ISO & IEC maintain terminological data base for use in standardization mentioned in ISO.
3.1	**Accessory**	Component inside the container (3.4) which is intended by the manufacturer to assist in the collection, or mixing, or separation of the specimen. (3.15)	----	
3.2	**Additive**	Substance (other than inside surface treatment designed to be irremovable) that is placed in the container (3.4) in order to facilitate the creation of the desired sample.	**2.5** Any ingredient including tube coating or closure coating or anticoagulant or any other material that is placed in the tube.	In IS 10916 mention additive including tube coating & closure coting while in ISO additive mention only substance(additive)
3.3	**Closure**	Components by which the container (3.4) is sealed, which may consist of several parts.	**2.3** The component by which the tube of container is closed and vacuum maintained in the tube.	
3.4	**Container**	Vessel, whether evacuated or not, intended to contain a specimen (3.15) together with any container accessory (3.1) and additive (3.2) with closure (3.3) in place.	**2.1** The vessel to contain the specimen.	
3.5	**Container interior**	Inner surface of the container (3.4) exposed to the specimen (3.15)	**2.4** Those inside surface of the tube & closure which come into contact with the blood specimen.	
3.6	**Draw volume**	Volume of whole blood that will be collected in the container (3.4)	-----	
3.7	**Evacuated container**	Container (3.4) intended for blood collection by means of evacuation either already induced by the manufacturer (i.e. pre-evacuated containers) or induced by the user before or during blood collection.	-----	
3.8	**Expiry date**	Date after which the product shall not be used.	-----	
3.9	**Fill indicator**	Line marked on a tube (3.16) or its label to indicate the correct filling.	-----	

Clause		ISO 6710:2017	IS 10916:1984	Remark
3.10	**Free space**	Space above the drawn sample	-----	
3.11	**Nominal liquid capacity**	Draw volume (3.6) plus volume of additive (3.2) not including any accessories.	-----	
3.12	**Primary colour**	Dominant color of closure (3.3) components most representative of the additive (3.2) in the container (3.4)	-----	
3.13	**Primary pack**	Smallest package of container (3.4)	-----	
3.14	**Relative centrifugal force RCF**	Force that is generated during the sample centrifugation process which is specified by the manufacturer for adequate separation.	-----	
3.15	**Specimen**	Venous blood collected in a container (3.4)	-----	
3.16	**Tube**	Part of the container (3.4), without the closure (3.3), that contains the specimen (3.15)	**2.2** The glass tube of the container that contain the specimen.	In IS 10916 mention container as a glass tube.
3.17	**Visual inspection**	Inspection by an observer with normal or corrected-to-normal vision without magnification under a uniform illuminance between 500 lx and 1000 lx.	-----	
		----	**2.6 Sterile –** Describe the condition of the interior of a container which has been subjected to an approved sterilizing process. **2.7 Holder –** In which evacuated tube will slide for obtaining blood specimen. The holder may be of fix type or screwed type. The fix type is for single use only. **2.8 Needle –** Double pointed needle with a hub which shall fit the holder, & puncture the closure of the container for obtaining the blood specimen. **2.9 Sheath** - Sleeve type covering for the needle.	point 2.6 to 2.9 not mention in ISO 6710.
4	**Materials**		**3 Materials**	
4.1		The tube shall be made of material which allows a clear view of the contents when subjected to visual inspection unless exposure to ultra violet light or visible light would degrade the contents.	**3.1** The tube of container shall be made from clear transparent glass other than soda lime glass that allows an adequate undistorted view of the contents. It shall have sufficient physical strength to withstand normal use. It shall be capable of maintaining the required vacuum for the stated self-life.	In IS 10916 only glass tube while in ISO refer that the tube shall be made of material which allows a clear view of the contents. (Mostly PET material is used for tubes currently)

Agenda for 18th meeting of the Medical Laboratory Instruments Sectional Committee (MHD 10)
(*For BIS use only*)

Clause		ISO 6710:2017	IS 10916:1984	Remark
4.2		The tube shall be made of material which allows a clear view of the contents when subjected to visual inspection unless exposure to ultra violet light or visible light would degrade the contents. For the determination of specified metals and other specified substance, the formulation of the closure material should be such as not to interfere with the determination thereby affecting the results. For highly sensitive determination (for example those using fluorimetry) or little used tests, limit of interference may not have been agreed on. In such cases the laboratory should establish a blank value and consult the manufacturer	**3.2** The closure of the container system shall be made of the rubber used for medical purpose. It shall provide for the needle puncture and reseal. It shall whole vacuum for stated self-life. **3.3** All material used in the construction of the container & any additive & coating shall not influence the result obtained when the container is used as intended. **3.4** Holder material shall be either glass or plastic. **3.5** Needle cannula material shall be of stainless steel as specified in IS 3317-1983. **3.6** Needle hub & its Sheath may be of plastic material.	In IS 10916 clause 3.4 to 3.6 is refer for holder, cannula and hub.
4.3		The container shall be free from foreign matter when subjected to visual inspection.	----	
5	**Draw volume**	When tested in accordance with the methods specified in Annexure A & B, the volume of water should be within ±10 % of the draw volume. If ±10 % of draw volume is not met throughout the shelf life, the manufacturer shall ensure that correct result shall be obtained.	4.2 The vacuum draw test specified in appendix –A shall apply to all type of container when tested by the method described in appendix – A. the volume of water used shall be within ±5 % of the nominal capacity of the container. This shall be a type test.	Draw volume tolerance is ±10 % in ISO 6710 while in IS 10916 it is only ±5 %
6	**Design**			
6.1		The closure shall not become loose during mixing when tested for leakage in accordance with the method in Annexure- C or other equivalent method and no fluorescence shall be detectable in the water in which the container has been immersed.	**4.1** Exterior of tube and closure shall be so designed as to allow for use with blood collecting needle and holder.	
6.2		Where a closure is intended to be remove, it shall be designed that it can be removed by gripping with the fingers and/or by mechanical means, so that the part of closure that could be in contact with the specimen is not touched.	**5.1** The closure shall be so designed that it can be removed by gripping with fingers or by mechanical extractors. **5.2** The closure shall be so designed that shall not be removed or loosened when use to collect a blood specimen with a blood collecting needle.	

Clause		ISO 6710:2017	IS 10916:1984	Remark
6.3		Consideration in the design shall be given to ensure compatibility with transportation system, processes, pre analytical and analytical automation.		
		----	**4.5** The capacity and dimensions of glass tube shall be in accordance with Table 1. **4.6** The double pointed needle with hub shall have diameter and length in accordance with table 2. **4.7** The both ends of the needle shall have short bevel in accordance with IS: 3317-1983 **4.8** These needles are for single use only. **4.9** Minimum length of the holder from its shoulder shall be in accordance with table 3. **4.10** If the needle is not fixed in the Luer tip of the holder and the hubbed needle are used there shall be sufficient threads both on the needle hub and on the tip of the holder so that the needle is locked in place with the mating holder. **4.11** When the multiple sample needle is used, the needle end in the rear of the hub is covered by the thin wall natural rubber tubing 1 to 2 mm more than its exposed length. Its shall be capable of collapsing when the needle is punctured into closure and with its elasticity it close the exposed length of the needle completely when tube is withdrawn along with closure. **4.12** Sheath sleeve dimensions shall be such that it is minimum 2 mm more than the exposed length of the needle on both sides.	In IS 10916 clause 4.5 to 4.12 is refer for glass tube capacity and blood collection needle, which is not mentioned in ISO
7	**Construction**			
7.1		The container holding the specimen shall not break/crack or leak when centrifuge at an RCF of 3000g or the value specified by the manufacturer for the intended use, when tested in accordance with the method specified in annexure-D.	**5.3** The container holding the specimen, when centrifuged shall be capable of withstanding an acceleration of 3000g in a longitudinal axis for 10 minutes.	
7.2		When subjected to visual inspection, the container shall not have a sharp edge, projection or surface roughness capable of accidentally cutting, puncturing or abrading the skin of the user.		
		Not mentioned	**5.5** The holder shall have outward flange on the one end. The flange shall have two flat sides- one opposite the other to prevent rolling of holder. The flange shall be of ample size to give a finger hold. **5.6** Needle shall be fitted concentric in the holder. The cannula shall be as specified in IS 3317- 1983. **5.7** Container, needle and holder shall be free from foreign matter. **5.8** The proximal end of the tube shall be suitably shaped to form a flat or concave surface to facilitate the thumb pressing it.	In IS 10916 clause 5.5 to 5.8 is refer for needle holder and blood collection needle, which is not mentioned in ISO

Clause		ISO 6710:2017	IS 10916:1984	Remark
8	**Sterility and special microbiological states**			
8.1		For evacuated containers, the interior shall be sterile if unused. The container interior and accessory or additive shall be subjected to a validated process designed to achieve sterility.	**6.1** All container shall be sterilized and shall satisfy the requirements of IS: 10150-1981. The container shall maintain the sterility for the stated life.	
8.2		For non-evacuated containers, if a manufacturer claims that the interior of the unopened and unused container, or the whole container, is sterile or has a special microbiological state, the container interior and any accessory or additive shall be subjected to a validate process designed to achieve that claim.	**----**	
8.3		For non-evacuated container with microbe-supporting additives, such as trisodium citrate or citrate phosphate dextrose adenine, solution shall be subjected to a validated process to remove or to render non-viable microbes in the additive and the container interior.	**----**	
		----	**6.2** Where hubbed needles are supplied separately in sheath the needle and the interior of the sheath shall be sterile and shall satisfy the requirements of IS: 10150-1981. The sheath and the needle shall maintain the sterility for the stated shelf life. **6.3** Where needles are fixed in the holder, there shall be a sheath for this needle and the complete holder with needle shall satisfy the sterility requirements of IS: 10150-1981 and they shall maintain the sterility for the stated shelf life.	In IS 10916 clause 6.1 to 6.3 is refer for blood collection needle sterility requirement, which is not mentioned in ISO
		----	**7. Limits of interference** **7.1.1** Testing for contaminants shall be carried out according to the latest Indian Pharmacopoeia or by means of a definitive or reference method where such method is available. If there is no available definitive or reference method then a method in usage may be used provided that the method is specified.	
9	**Additives**			
9.1		The stated nominal amount of additive shall be within the range specified in Annexure-E	9.1. When one of the anticoagulant specified in Appendix C is used, the concentration shall be as indicated therein.	
9.2		For container with an additive, provision shall be made for mixing by using the free space bubble to facilitate agitation or by some other physical means.	----	

Clause		ISO 6710:2017	IS 10916:1984	Remark
9.3		The free space in containers for coagulation testing should not impact the analytical result. The manufacturer should assess the risk associate with the free space in the correctly filled container.	**4.3** For containers without an additive there shall be sufficient free space (minimum 2 percent of its capacity) to allow adequate mixing by mechanical or manual means. **4.4** For containers with an additive there shall be sufficient free space (not less than 2 percent and not more than 15 percent of its capacity) to allow adequate mixing by mechanical or manual means	In IS 10916 free space is mention with specification while in ISO manufacturer should ensure correctly filling & the risk associate with the free space.
10	**Marking and labeling**			
10.1		Non-transparent label shall not completely encircle the tubes.	----	
10.2		The marking and labeling on the container shall remain adherent over its shelf life, under storing conditions as specified by the manufacturer.	----	
10.3		Each primary pack shall be marked on the outside at least with the following information:	11.1. Each shelf pack shall be marked with the following	
	a.	The manufacturer's or supplier's name or trade mark.	11.1 (a) Name, address and recognized trade mark of the manufacturer.	
	b.	The batch number;	11.1 (b) Batch number	
	c.	The expiry date which should be expressed in the format YYYY-MM or YYYY-MM-DD;	11.1 (c) Date of manufacture or expiry date	
	d.	A description of the contents which shall include the following: - The nominal liquid capacity or draw volume. - The letter code (see Clause 11) and/or product name and/or description of content. - The words "STERILE" or the appropriate graphical symbol according to ISO 15223-1 if the manufacturer claims that the unopened container interior and any contents of the container are sterile. - The word "Single-use only" or the appropriate graphical symbol according to ISO 15223-1. - Storage requirements. - Labeling requirements from the local legislation.	11.1 (d) Description of contents 11.1 (e) Storage condition	
10.4		If a container is provided specifically for the determination of a certain substance, the maximum level of contamination with that substance shall be stated on the label, the primary pack or in the supporting information.	**7.1** Where containers are provided for the estimation of specific substances, such as sodium, potassium, etc. They may be labelled as being free from contamination if they give a concentration of that substance which is less than 1 percent of the level of the mean of the reference range for that substance.	

Clause		ISO 6710:2017	IS 10916:1984	Remark
10.5		If a container has a liquid additive, its volume shall be stated on the label, the primary pack or in the supporting information.	9.2. At the time of use with an anticoagulant the amount of blood collected shall be ±5 percent of the stated volume. If antimycotic agents are added to liquid additive in the tube for growth inhibition and preservation of sample , the package label shall reflect such additive.	
10.6		Container shall have the following information marked directly onto the tube or on the label: a) The manufacturer's or supplier's name or trademark. b) The batch number. c) The letter code (see Clause 11) and/or product name and/or description of the contents.	-	
		d) The expiry date which should be expressed in the format YYYY-MM or YYYY-MM-DD. e) The nominal liquid capacity or draw volume, specified where appropriate on the container. f) The words "Single-use only" or the appropriate graphical symbol according to ISO 15223-1. g) A fill indicator: if that is not possible, information on how to fill the container correctly shall be provided on the primary pack or in the supporting literature. h) The words "STERILE" or the appropriate graphical symbol according to ISO 15223-1 if the manufacturer claims that the unopened and unused container interior and any contents of the container are sterile.	-	
10.7		If the container is intended to be stored or used, under specific condition this shall be clearly stated on the container or on the label and/or on the supporting literature in the primary pack.	-	
			12. Packing	
			12.1. Each shelf pack shall be packed as agreed to between the purchaser and the manufacturer. However the requirement of packing as specified in IS 10150-1998 shall be followed.	
11	**Container identification**			
		Container shall be identified by mean of the letter code and/or a description for the additive and accessories given in table-1 and/or, product name. where there are additive and accessories other that those in table-1, container shall be identified by means of the description of the additive and/or product name. Recommended colour code for identified additive and accessories are provided in annexure--f	10.1. The following code indicate whether or not an anticoagulant has been used, and identifies the anticoagulant by the use of a letter coding. 10.2. The volume in ml the container is designed to hold, shall be added after the code letters. 10.3. Code of anticoagulant shall be marked according to 10.1 separately. 10.4. And if any other additive is added in the container it shall be marked separately.	

Clause		ISO 6710:2017		IS 10916:1984		Remark
	Table-1 (letter code for identifying additives and accessories)			**10. Anticoagulant code**		
	Additive/accessory		**Letter code**	**Anticoagulant**	**Code**	
	EDTA dipotassium salt tripotassium salt		K2E K3E	EDTA	KE	In ISO EDTA coding is K2E and K3E while in IS 10916 it is denoted by KE
	Trisodium citrate 9 :1		9NC	Trisodium citrate	9NC	
	Trisodium citrate 4 :1		4NC	Trisodium citrate	4NC	
	Fluoride oxalate Fluoride EDTA Fluoride heparin Fluoride, citric acid		FX FE FH FC	Fluoride oxalate - - -	FX - - -	
	Lithium heparin Lithium heparin and Gel Sodium heparin		LH LH NH	Lithium heparin - Sodium heparin	LH - NH	
	Citrate phosphate dextrose adenine Acid citrate dextrose		CPDA ACD	- Acid citrate dextrose	- ACD	
	Clot activator Clot activator wit Gel		CAT CAT	- -	- -	
	None		Z	None	Z	
	-		-	Potassium oxalate	KX	
	-		-	Ammonium and potassium oxalate	AKX	

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Comparison of annexure

ISO 6710:2017	IS 10916:1984	Remark
Annexure-A (Draw volume test for non-evacuated container)	Appendix - A (Clause 4.2) Vacuum draw test	
Annexure-B (Draw volume test for non-evacuated container)		
Annexure-C (Test for leakage container) annexure C enclosed. **C.3.4** Rotate the container on the roller type mixture for 2 minutes or mix as recommended by the manufacturer of the container. Immerse the container upside down in a tank containing not more than 100 ml of water to cover the closure completely. Leave at between 15 °C to 20 °C for 60 minutes. Remove the container from the water and examine the water under UV light.	Appendix - B (Clause 8.1 and 8.2) **B-3.3** Expose the inverted container and contents for 2 hours to a temperature of -20 to +4 °C. Allow to return to room temperature and then expose to 37 °C for 2 hours. Immerse the inverted container in the minimum quantity of water to completely cover the closure and check for traces for fluorescein by ultra violet light.	Test procedure has been different in ISO as compare with IS 10916
Annexure-D (Test for robustness of the container)	-	Not available in IS 10916
Annexure-E (Concentration of additives and volume of liquid additives) **E.2** Specification for dispensing additive in EDTA – 1.2 -2 mg/ml of blood **E.3.1** Tri-sodium citrate The solution of tri-sodium citrate dehydrate used for the preparation of blood collection tube shall have a concentration within the range of 0.100 mol/l to 0.136 mol/l. **E.4 Fluoride oxalate –** Blood concentration of Potassium Oxalate monohydrate shall be within the range of 1 to 3mg/ml and for Sodium fluoride Shall be within the range of 1 to 4 mg/ml - **E.5 Fluoride/EDTA –** Blood concentration of EDTA free acid shall be within the range of 1.2 – 2 mg/ml and for Sodium fluoride Shall be within the range of 1 to 4 mg/ml **E.6 Fluoride /heparin –** Blood concentration of heparin shall be within the range of 10 – 30 I.U/ml. Sodium fluoride Shall be within the range of 1 to 4 mg/ml **E.7 Heparin sodium and Heparin Lithium –** Blood concentration of heparin shall be within the range of 10 – 30 I.U/ml	Appendix – C (Clause – 9.1) **C-1.1(a)** Specification for dispensing additive in EDTA – 1.9 ± 0.2 mg/ml of blood **C-1.1 (d)** Tri-sodium citrate solution at a concentration of 0.109 ± 0.010 mol/l **C-1.1(b)** Blood concentration of Potassium Oxalate monohydrate shall be within the range of 3.0 ± 0.3 mg/l and for Sodium fluoride Shall be within the range of 1.0 ± 0.1 mg/l. **C-1.1(c)** Blood concentration of ammonium Oxalate shall be within the range of 1.2 ± 0.12 mg/l and for potassium oxalate Shall be within the range of 0.8 ± 0.08 mg/l - **C-1.1 (e) Heparin –** 15 ±2.5 I.U/ml of blood. **C-1.1 (e) Heparin –** 15 ±2.5 I.U/ml of blood	Dispensing qty. of chemical is different in both. Range of preparation qty. of chemical is different in both Range of preparation qty. of chemical is different in both - - In ISO heparin range is10 – 30 I.U/ml while in IS 10916 it is 15 ±2.5 I.U/ml. In ISO heparin range is10 – 30 I.U/ml while in IS 10916 it is 15 ±2.5 I.U/ml.

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ISO 6710:2017			IS 10916:1984		Remark
E.8. Citrate phosphate dextrose adenine (CPDA) – **E.8.1 T**he formulation shall be as follows**:**			**C-1.1 (f) Acid citrate dextrose**		
Additive component		**Amount**	**Additive component**	**Amount**	
Citric acid (anhydrous)		2.99 g	Citric acid (monohydrate)	8 g	Quantity of citric acid is more in IS 10916
Tri-sodium citrate (dehydrate)		26.3 g	Tri-sodium citrate (dehydrate)	22 g	Quantity of Tri sodium citrate is less in IS 10916
Monobasic sodium phosphate (monohydrate)		2.22 g	-	-	Not mentioned in IS10916
Dextrose (monohydrate)		31.9 g	Dextrose	25 g	Quantity of Dextrose is less in IS 10916
Adenine		0.275 g	-	-	Not mentioned in IS10916
Purified water		Sufficient volume to create a final solution of 1000 ml	Purified water	1000 ml	
E.8.2 – Six volume of blood shall be added to 1 volume of CPDA solution			-		Not mentioned in IS10916
E.8.3 – The permitted tolrence on the specified volume of additive shall be within ±10 %**.**			-		
Annexure – F (Recommended color code for identifying and accessories)					
Additive/accessory	**Letter code**	**Recommended primary colour of closure**			
EDTA dipotassium salt tripotassium salt	K2E K3E	Lavender Lavender	-		Colour code not mentioned in IS 10916
Trisodium citrate 9 :1	9NC	Light blue	-		
Trisodium citrate 4 :1	4NC	Black	-		
Fluoride oxalate Fluoride EDTA Fluoride heparin Fluoride, citric acid	FX FE FH FC	Grey Grey Grey Pink	-		
Lithium heparin Lithium heparin and Gel Sodium heparin	LH LH NH	Green Light green Brown	-		
Citrate phosphate dextrose adenine Acid citrate dextrose	CPDA ACD	Yellow Yellow	-		
Clot activator Clot activator wit Gel	CAT CAT	Red Dark yellow	-		
None	Z	White	-		

Annex 6

Program of Work

MHD 10: Medical Laboratory Instruments

Scope: To formulate Indian Standards for medical laboratory instruments and medical laboratory equipments and glasswares in all in-vitro diagonistics medical laboratories including clinical-pathology, hematology, histopathology, cytopathology, flow-cytometery, biochemistry, microbiology and molecular biology

Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS 3055 (Part 1) : 1994	Clinical thermometers: Part 1 solid stem type - Specification (Second Revision)	February, 2021	5	Indigenous
2	IS 3055 (Part 2) : 2004	Clinical thermometers: Part 2 enclosed scale type - Specification (Third Revision)	November, 2019	-	Indigenous
3	IS 3740 : 1966	Specification for tubes, glass, for pathological work	March, 2022	-	Indigenous
4	IS 3741 (Part 1) : 1990	Medical instruments sedimentation tubes - Specification: Part 1 westergren tube (Second Revision)	February, 2016	-	Indigenous
5	IS 3741 (Part 2) : 1990	Medical glass instruments - Sedimentation tubes - Specification: Part 2 wintrobe tube (Second Revision)	February, 2021	-	Indigenous
6	IS 3742 : 1990	Medical glass instruments - Pipettes, dilution for haemocytometers specification (Second Revision)	February, 2021	-	Indigenous
7	IS 4067 : 1967	Specification for tube, swab (West Type), for throat	March, 2022	-	Indigenous
8	IS 4069 : 1967	Specification for urinometer	March, 2022	-	Indigenous
9	IS 4087 : 1980	Specification for pipette for haemoglobinometers and blood pipette for biochemical work (First Revision)	March, 2022	-	Indigenous
10	IS 4364 : 1967	Specification for pipettes, serological	March, 2022	-	Indigenous
11	IS 4381 : 1967	Specification for pathological microscope	March, 2022	3	Indigenous
12	IS 4444 : 1967	Specification for bottles, bacteriological	March, 2022	1	Indigenous

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S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
13	IS 4529 : 1968	Specification for glass tubes for medical thermometers	January, 2018	-	Indigenous
14	IS 4708 : 1968	Specification for urine glass, conical	March, 2022	-	Indigenous
15	IS 4754 : 1968	Specification for staining troughs and jar	March, 2022	-	Indigenous
16	IS 5155 : 1969	Specification for pipettes, ostwald - Folin type	March, 2022	-	Indigenous
17	IS 6606 : 1972	Albuminometer (Esbach's) with Stopper, Stand and Case	March, 2022	-	Indigenous
18	IS 6942 : 1973	Specification for flask, roux, bacteriological, with or withoutoffset neck (1000 Ml Nominal Capacity)	March, 2022	-	Indigenous
19	IS 6943 : 1990	Medical glass instruments - Coverglass used with hemckytometer - Specification (Fw Reviiim)	February, 2022	-	Indigenous
20	IS 6944 : 1973	Specification for bottle, bijou, bacteriological	March, 2022	-	Indigenous
21	IS 7039 : 1973	Specification for tube, culture, screw cap	March, 2022	-	Indigenous
22	IS 7183 : 1973	Specification for flask, culture, haffkine	March, 2022	-	Indigenous
23	IS 8501 : 1977	Specification for anaerobic jar	March, 2022	-	Indigenous
24	IS 9430 : 1980	Specification for tube, haemometer	March, 2022	-	Indigenous
25	IS 10269 : 1982	Specification for haemocytometercounting chambers clinical and diagnostic apparatus	May, 2022	-	Indigenous
26	IS 10615 : 1983	Needle Holder, Bozemann's Pattern	March, 2017	-	Indigenous
27	IS 10867 : 2018 ISO 6710: 2017 ISO 6710: 2017	Single - Use containers for humanvenous blood specimen collection (First Revision)	-	-	Identical under dual numbering
28	IS 10916 : 1984	Specification for evacuated tubesfor blood specimen - Collection (Vacutainers)	March, 2022	-	Indigenous

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29	IS 11383 : 1985	Specification for thin walled glass capillary pipettes	December, 2022	-	Indigenous
30	IS 12622 : 1989	Medical thermometers for hypothermia, subnormal range - Specification	February, 2021	-	Indigenous
31	IS 14284 : 1995 ISO 7712 ISO 7712	Laboratory glassware - Disposablepasteur pipettes - Specification	February, 2021	-	Identical under dual numbering
32	IS/ISO 17593 : 2007 ISO 17593:2007	Clinical laboratory testing and in vitro medical devices - Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy		-	Identical under single numbering

Drafts Standards in WC Stage		
SI. No.	**Doc No.**	**Title**
1	MHD 10 (21498) Revision of: IS 10269:1982	Medical Laboratory Glass Apparatus-Haemocytometer-Specification First Revision
2	MHD 10 (21767) Revision of: IS 4067:1967	Medical Laboratory Glassware Throat Swab Tube West-type Specification
3	MHD 10 (21771) Revision of: IS 4069:1967	Medical laboratory Glassware Urinometer - Specification First Revision
4	MHD 10 (21774) Revision of: IS 4087:1980	Medical Laboratory Glassware Pipette for Haemoglobinometer and Blood Pipette for Biochemical Work - Specification Second Revision
5	MHD 10 (21785) Revision of: IS 4708:1968	Medical Laboratory Glassware Conical Urine Glass - Specification First Revision
6	MHD 10 (21786) Revision of: IS 6943:1990	Medical Laboratory Glassware - Cover Glass used with Haemocytometer Specification Second Revision
7	MHD 10 (21839) Revision of: IS 4754:1968	Medical Laboratory Glassware Staining Troughs and Jar - Specification First Revision
8	MHD 10 (21841) Revision of: IS 6606:1972	Medical Laboratory Glass Apparatus Esbachs Albuminometer Specification First Revision
9	MHD 10 (22499) Revision of: IS 4444:1967	Medical Laboratory Glassware Bacteriological Bottles Specification first revision

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Draft Standards Completed WC Stage		
SI. No.	**Doc No.**	**Title**
1	MHD 10 (21775) Revision of: IS 4444:1967	Medical Laboratory Glassware Serological Pipettes - Specification First Revision

Finalized Draft Indian Standard		
SI. No.	**Doc No.**	**Title**
1	MHD 10 (21745) Revision of: IS 3740:1966	Medical Laboratory Glassware Glass Tubes for Pathology Work - Specification First Revision

Finalized Draft Indian Standards under Print		
SI. No.	**Doc No.**	**Title**
1	MHD 10 (22119) Revision of: IS/ISO 17593:2007	Clinical Laboratory Testing and in Vitro Medical Devices Requirements for in Vitro Monitoring Systems for Self-Testing of Oral Anticoagulant Therapy First Revision

Total Published Standards:32 Total Standards Under development:12