<u>BUREAU OF INDIAN STANDARDS</u> <u>MEDICAL EQUIPMENT AND HOSPITAL PLANNING</u> <u>DEPARTMENT (MHD)</u>

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time			
Medical Laboratory Instruments Sectional Committee (MHD 10)	21	11:00 AM, 09 April 2024, Tuesday			
via Webex platform					
Meeting Link:					
https://bismanak.webex.com/bismanak/j.php?M1	<u>[]]=mc82d651</u>	7 <u>d4f29b7cceb524f80a95eff1</u>			
Meeting Id: 2517 346 5260					
Password: MHD10@21 (64310121 from video systems	3)				
Chairperson	Ν	Iember Secretary			
Dr. Sudip Kumar Datta	Mr. Pawan Ku	mar			
Additional Professor and Head,	Scientist B/Ass	sistant Director,			
Department of Laboratory Medicine,	Medical Equip	ment and Hospital Planning			
AIIMS, New Delhi	Department, B	ureau of Indian Standards			

ITEM 0 GENERAL

0.1 WELCOME ADDRESSES BY BIS

0.2 OPENING REMARKS BY CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

- 1.1 The minutes of the last (20th) meeting of Medical Laboratory Instruments Sectional Committee (MHD 10) held on 06 Feb 2023 via Webex VC, duly approved by the Chairperson was circulated to all members dated 11 Mar 2024.
- 1.2 No comments have been received so far.

The Committee may formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The present scope of Medical Laboratory Instruments Sectional Committee (MHD 10) is as follows:

- 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

The Committee may please note.

2.2 The present composition of Medical Laboratory Instruments Sectional Committee (MHD 10) along with participation status of members is enclosed at <u>Annexure 1</u>.

2.3 As per the decision taken during the previous meeting, follow-up was made with the following members who have not participated in the last two meetings and the status is given below:

Sl. No.	Organisation	Principal Member	Alternate Member	Status
1	National Institute of Pathology, New Delhi	Dr. Sandeep Agrawal	Dr. Garima Jain	Membership terminated on attendance

2.4 Requests have been received from the following for representation on the Committee:

Sl. No.	Organisation	Nomination
1.	Siemens Healthcare Private Limited,	Nivedita Mitra, Senior Key Expert
	Bangalore	

2.5 With a view to make the Committee more effective through active contribution of the members in standardization activities, non-participating members are liable to be dropped from the Committee in order to provide opportunity to other similar organizations/institutions that may be interested to participate and contribute to the standardization efforts. Further, the Committee needs to be made fully representative of the various interests concerned considering that non-industry representation should not be less than two-thirds of the committee composition, as far as possible.

The committee may please note and review the composition.

ITEM 3 DRAFT INDIAN STANDARDS UNDER PRINT

Sl. No.	Document No.	Title	
1 MHD 10 (2	MHD 10 (22/99)	Medical Laboratory Glassware Bacteriological Bottles	
	MHD 10 (22499)	Specification first revision	

ITEM 4 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

4.1 There are no draft Indian Standards/amendments under wide circulation.

ITEM 5 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

5.1 The following draft Indian Standards / Amendments are ready for wide circulation:

Sl.	Document No./	Title	Romarks
No.	Standard No.	The	Nemai K5
1.	IS 5155	Specification for pipettes, ostwald - Folin type	Revision
2	IS 6042	Specification for flask, roux, bacteriological, with	Davision
2. IS 6942		or without offset neck (1000 ml Nominal Capacity)	Kevision
3.	IS 6944	Specification for bottle, bijou, bacteriological	Revision
4.	IS 7039	Specification for tube, culture, screw cap	Revision
5.	IS 8501	Specification for anaerobic jar	Revision
6.	IS 9430	Specification for tube, haemometer	Revision
7.	IS 11383	Specification for thin-walled glass capillary pipettes	Revision

ITEM 6 DRAFT UNDER PREPARATION

In the following drafts are currently under preparation:

- 1. Clinical centrifuges (IEC 61010-2-020:2016 RLV)
- 2. LBC (liquid-based cytology) brush
- 3. Lab plasticware filter tips for standard pipettes
- 4. Multiprobe Ultrsonicator
- 5. Gradient thermocycler
- 6. Platelet Incubator with Agitator
- 7. Anaerobic Workstation
- 8. Vortex Mixer (IEC 61010-2-051:2018, IEC 61010-2-051:2018 RLV)
- 9. Double Beam UV Spectrophotometer (IEC 61010-2-061:2018 RLV)
- 10. HPLC System specifications

- 11. GC-MS SQD with Liquid Autosampler and Headspace
- 12. Quaternary FHPLC

The committee may deliberate and decide.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

7.1 Comments on IS 4381 : 1967 Specification for pathological microscope was received from Magnus Opto Systems India Pvt. Ltd. and attached at <u>Annexure 2</u>.

7.2 Comments on IS 7183 : 1973 Specification for Flask, Culture, Haffkine was received from ShrivSatish Chitriv (BOROSIL LIMTED) and attached at *Annexure 3*.

7.3 Comments on IS 7039 : 1973 Specification for Tube, Culture, Screw Cap was received from Shri Satish Chitriv (BOROSIL LIMTED) and attached at <u>Annexure 4</u>.

The Committee may kindly deliberate.

ITEM 8 NEW SUBJECTS

8.1 The committee may identify the emerging fields in the area under its scope and decide formulation of Indian Standards on the same. The Committee may also 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 kindly deliberate.

- 8.2 Following new subjects for formulation of Indian Standard are proposed:
 - Refrigerated Superspeed Centrifugation system.
 - High speed centrifuge
 - Mini centrifuge
 - Stacked variable-temperature incubator shaker.
 - Water jacketed CO2 Incubator
 - Rotary shaker
 - Pipette Controller
 - 384 Well white frame plates
 - Pipette controllers with double safety valve and hydrophobic filter.
 - Microloader tips
 - Dual Platform Rocker

- Sledge microtome
- Gel documentation system.
- μ-Slide
- Handheld pH Meter with probe
- Magnetic stirrer
- Test tube mixer (tube rotator/rotating)
- Rocker shaker/reciprocal shaker
- UV transilluminator

The Committee may kindly deliberate and decide.

8.3 In the 19th meeting the members inquired about any specific priority areas for establishing standards within the realm of medical devices. It is being informed that medical laboratory instruments, as outlined in a recent notification by CDSCO (attached at Annexure C), will be accorded priority in the formulation of standards.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 As MHD 10 does not have liaison with international technical committees, members are encouraged to identify any suitable ISO committee having scope similar to MHD 10.

9.2 ISO/TC 76, titled "Transfusion, infusion, and injection, and blood processing equipment for medical and pharmaceutical use," serves as the ISO Technical Committee overseeing standards in this domain. Within the national framework, MHD 12 functions as the National Mirror Committee for this technical area. Additionally, MHD 10 collaborates closely with the working group ISO/TC 76/WG 2, which focuses on "Rigid container systems and related accessories for parenterals and injectables.

To enhance coordination and standard development within MHD 10, it is proposed to register Dr. Sudip Kumar Datta, Chairperson MHD 10 as an expert for ISO/TC 76/WG 2. His role would involve contributing expertise to standard development efforts and facilitating maintenance activities relevant to standards in alignment with MHD 10 scope.

ITEM 10 TECHNICAL ISSUES

It is learnt that large volumes of vacutainers is being produced domestically and it is imperative to ensure their quality and interoperability. In light of this, it is proposed to recommend the line ministry to issue a Quality Control Order (QCO) for IS 10867:2018 (ISO 6710:2017). Following the implementation of the QCO, adherence to IS 10867:2018 (ISO 6710:2017) will

become mandatory for manufacturers. Implementing such a QCO will serve several critical purposes:

- Enhanced Safety and Quality: Standardizing vacutainer production according to IS 10867:2018 (ISO 6710:2017) will ensure that these medical devices meet rigorous safety and quality standards. This will reduce the risk of defects or substandard products reaching healthcare facilities and patients, ultimately safeguarding public health.
- Improved Interoperability: Ensuring compliance with international standards promotes interoperability among vacutainers and associated medical equipment. This means that vacutainers manufactured in line with IS 10867:2018 (ISO 6710:2017) will be compatible with a wide range of medical devices, enhancing efficiency and reducing errors in laboratory processes.
- 3. **Reduction in Turnaround Time:** By adhering to standardized specifications outlined in IS 10867:2018 (ISO 6710:2017), manufacturers can streamline their production processes. Consistently manufactured vacutainers will lead to fewer discrepancies, minimizing delays in procurement, inventory management, and laboratory testing procedures. This, in turn, will contribute to faster diagnosis and treatment for patients, ultimately improving healthcare outcomes.

Given these reasons, recommending for a QCO for IS 10867:2018 (ISO 6710:2017) is crucial for ensuring the safety, quality, interoperability, and efficiency of vacutainer production and usage in the domestic market.

The Committee may kindly approve.

ITEM 11. PROGRAMME OF WORK

11.1 The present Program of Work of Medical Laboratory Instruments Sectional Committee
(MHD 10) is available at BIS website <u>www.bis.gov.in</u> > Standards > Program of Work > Select MHD and MHD 10 from the dropdown.

The Committee may kindly note.

11.2 Review of Indian Standards (pre-2000 Standards)

10.2.1 All the Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archived in the light of technological developments that have happened so far in relation to these standards. Following Indian standards are to be reviewed:

Sl No.	IS no.	Title	Status
1	IS 5155 · 1969	Specification for pipettes, ostwald - Folin	Ready for wide
1	15 5155 . 1707	type	circulation
		Specification for flask, roux,	Ready for wide
2	<u>IS 6942 : 1973</u>	bacteriological, with or without offset	circulation
		neck (1000 Ml Nominal Capacity)	
3	IS 6944 · 1973	Specification for bottle, bijou,	Ready for wide
5	10 07+1.1775	bacteriological	circulation
4	IS 7039 · 1973	Specification for tube culture screw cap	Ready for wide
т т	10 7037 . 1773	specification for tube, culture, selew cap	circulation
5	IS 8501 · 1977	Specification for anaerobic jar	Ready for wide
		specification for anacrobic jai	circulation
6	IS 9430 · 1980	Specification for tube haemometer	Ready for wide
0	15 7 150 : 1700	specification for tube, nacimonicier	circulation
7	IS 11383 · 1985	Specification for thin walled glass	Ready for wide
	10 11000 . 1700	capillary pipettes	circulation
8	<u>IS 14284 : 1995</u>	Laboratory glassware - Disposable	Standard reaffirmed by
0	<u>ISO 7712</u>	pasteur pipettes - Specification	ISO
		Medical glass instruments - Pipettes,	Comments received on
9	<u>IS 3742 : 1990</u>	dilution for haemocytometers	standard required to be
		specification (Second Revision)	resolved
10		Specification for tube, swab (West Type).	Comments received on
10	<u>IS 4067 : 1967</u>	for throat	standard required to be
			resolved
11	10 7102 1072		Comments received on
11	<u>IS 7183 : 1973</u>	Specification for flask, culture, haffkine	standard required to be
			resolved
10	10 1001 1007		Comments received on
12	<u>18 4381 : 1967</u>	Specification for pathological microscope	standard required to be
			resolved
12	IS 3055 (Part 1):	Clinical thermometers: Part 1 solid stem	Review Required
13	1994	type - Specification (Second Revision)	considering Minamata
		Madical instruments as dimentation takes	Draft un den num anstien
1 /	IS 3741 (Part 1) :	Specification: Dart 1 westergran tube	Dran under preparation
14	<u>1990</u>	(Second Pavision)	
		Medical glass instruments	Draft under preparation
15	IS 3741 (Part 2) :	Sedimentation tubes - Specification: Part	Dian under preparation
15	1990	2 wintrobe tube (Second Revision)	
	1		

The Committee may kindly deliberate.

11.3 Review of Indian Standards (as per 5-year cycle)

10.3.1 As per the policy of BIS, the Indian Standards which have completed five years since their last publication/reaffirmation, are to be reviewed by the concerned Sectional Committee for their reaffirmation/revision/withdrawal/amendment/archiving in the light of technological developments that have happened so far in relation to these standards.

10.3.2 With a view to improve the quality of standards formulation process and making it more evidence based, BIS envisions to undertake research and prepare a review document in respect of each of the Indian Standards which are due for revision.

10.3.3 Following Indian standards are to be reviewed under (as per 5-year cycle)

Sl No.	IS no.	Title	Status
	IS 3055 (Part 2) ·	Clinical thermometers: Part 2	Review Required
1	2004	enclosed scale type - Specification	considering
		(Third Revision)	Minamata convention

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

12.1 The following standards are identified by BIS secretariat for transfer from MHD 12 to MHD 10 as it is more relevant to the scope of MHD 10:

S.no.	IS No.	Title	Scope
1	IS 14193	Ovulation	This standard specifies requirements, methods of sampling and
		thermometers -	tests for ovulation thermometers of mercury-in-glass, maximum
		Specification	indicating. solid-stem type, intended for measurement-of deep
			body- temperature of human-beings.

The issue was discussed in the 20th meeting of MHD 10, It was noted during discussions that ovulation thermometers are not utilized in medical laboratories, thus it is suggested that they may not be incorporated into MHD 10. However, to ensure consistency among the standards across various sectional committees of MHD, it is recommended to include ovulation thermometers. This is in line with existing standards such as IS 12622:1989 for medical thermometers for hypothermia and IS 4529:1968 for specification of glass tubes for medical thermometers, which are already part of MHD 10.

In light of this, members were encouraged to share their perspectives on this matter within the week and comments were request via email dated 06 March 2024. The received comments will we discussed with the chairperson and the final decision will be informed during in the meeting.

12.2 In the 19th meeting of the MHD 10, the draft terms of reference for inviting R&D projects were allocated to subject experts and details are as follows:

S. No.	R&D title	Status
1	Study of Sample Collection Plastic Swab Tube	- Response received Under process to present before screening committee
2	Study of HPLC System specifications	- Under process to present before screening committee
3	Study of dilution Ultrapure Water Purification System specifications	- Under process to present before screening committee
4	Study of Platelet Incubator with Agitator specifications	 The document was presented to BIS screening committee and the same has been approved. The project is available for proposals (<u>link</u>) Last date for proposals 30 Apr 2024
5	Study of Anaerobic Workstation specifications	- Response received Under process to present before screening committee
6	Study of Vortex Mixer specifications	 The document was presented to BIS screening committee and the same has been approved. The project is available for proposals (<u>link</u>) Last date for proposals 30 Apr 2024
7	Study of Double Beam UV Spectrophotometer specifications	- Under process to present before screening committee
8	Study of Quaternary FHPLC specifications	- Response received Under process to present before screening committee
9	Study of dilution pipettes for haemocytometers specifications	- Response received Under process to present before screening committee
10	Study of sedimentation tubes (Westergren and Wintrobe) and ESR stand used for ESR computation	- Response awaited

The committee may deliberate and finalize the draft ToR.

ITEM 13 DATE AND PLACE OF NEXT MEETING

12.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD10 is scheduled on **Tuesday**, July 9, 2024.

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

S. No.	Organization	Member Name	Role	Attendance in last 3 meeting
1	All India Institute of Medical Sciences, New Delhi	Sudip Datta	Chairperson	3
	All India Institute of Medical Sciences, New Delhi	Tushar Sehgal	Alternate Member	
3	All India Institute of Medical Sciences, Mangalagiri	Dr Desai Vidya Sripad	Principal Member	
4	All India Institute of Medical Sciences, Mangalagiri	Dr. Sumit Rai	Alternate Member	0
5	All India Institute of Medical Sciences, Mangalagiri	Dr. Nichenametla Gautam	Alternate Member	
6	Association of Indian Medical Device Industry, New Delhi	C.S.Prasad	Alternate Member	2
7	Association of Indian Medical Device Industry, New Delhi	Manish Airan	Principal Member	2
8	Becton Dickinson India Private Limited, Gurugram	Sudhakar Mairpady	Principal Member	1
9	Becton Dickinson India Private Limited, Gurugram	Nitilesh Kumarii	Alternate Member	I
10	Bharati Vidyapeeth Medical College, Pune	Col Mahadevan Kumar	Principal Member	2
11	Bharati Vidyapeeth Medical College, Pune	Meghana Khandu Padwal	Alternate Member	
12	Borosil Glass Works Limited, Mumbai	Satish Chitriv	Alternate Member	2
13	Borosil Glass Works Limited, Mumbai	Shri Jeevan Dogra	Principal Member	2
14	CSIR - National Physical Laboratory, New Delhi	Rajesh	Alternate Member	
15	CSIR - National Physical Laboratory, New Delhi	G. Sumana	Principal Member	2
16	CSIR - National Physical Laboratory, New Delhi	Tuhin Kumar Mandal	Young Professional	
17	CSIR - Central Scientific Instruments Organisation, Chandigarh	Neelesh Kumar	Principal Member	2
18	CSIR - Central Scientific Instruments Organisation, Chandigarh	Sanjeev Soni	Alternate Member	

Annexure 1 Composition Of Sectional Committee (MHD 10)

19	Directorate General of Health Services, New Delhi	Naresh Panchal	Principal Member	2
20	Dr D. Y. Patil Medical College, Hospital and Research Centre, Pune	Chandrashekhar G Raut	Principal Member	3
21	Dr Ram Manohar Lohia Hospital, New Delhi	Prof. Dr. Arvind Ahuja	Principal Member	
22	Dr Ram Manohar Lohia Hospital, New Delhi	Saswati Das	Alternate Member	2
23	Dr Ram Manohar Lohia Hospital, New Delhi	Arvind Kumar Achra	Young Professional	
24	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Praveen Kumar Sharma	Principal Member	3
25	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Upinder Vishen	Alternate Member	C.
26	ICAR - National Institute of Cancer Prevention Research, Noida	Ruchika Gupta	Principal Member	2
27	ICMR - National Institute of Immunohaematology, Mumbai	Dr. Bipin Prakash Kulkarni	Principal Member	
28	ICMR - National Institute of Immunohaematology, Mumbai	Dr. Anindita Banerjee	Alternate Member	2
29	ICMR - National Institute of Immunohaematology, Mumbai	Dr. Umair Bargir	Young Professional	
30	Indian Council of Medical Research, New Delhi	Dr. Suchita Markan	Principal Member	2
31	Kalam Institute of Health Technology, Vishakhapatnam	Pramod	Young Professional	
32	Kalam Institute of Health Technology, Vishakhapatnam	Suraj Suresh Naik	Principal Member	2
33	Kalam Institute of Health Technology, Vishakhapatnam	Sruthi Saladula	Alternate Member	
34	Magnus Opto Systems India Private Limited, New Delhi	Shri Harmeet Singh Ahuja	Principal Member	2
35	Magnus Opto Systems India Private Limited, New Delhi	Shri Deepak Yadav	Alternate Member	2
36	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Gayathri S	Principal Member	2

37	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Shri Ashok Kumar	Alternate Member	
38	National Centre for Disease Control, New Delhi	Smt. Dr. MONIL SINGHAI	Principal Member	2
39	National Centre for Disease Control, New Delhi	Dr. Shubha Garg	Alternate Member	2
40	Post Graduate Institute of Medical Education and Research, Chandigarh	Bikash medhi	Principal Member	2
41	Remi Elektrotechnik Limited, Mumbai	Sunil Saraf	Principal Member	
42	Remi Elektrotechnik Limited, Mumbai	Suhas Kulkarni	Alternate Member	2
43	Remi Elektrotechnik Limited, Mumbai	Manoj Kumar Yadav	Young Professional	
44	Schott Glass India Private Limited, Pune	Shri Anand Bakshi	Principal Member	3
45	Schott Glass India Private Limited, Pune	Lalatendu Behera	Alternate Member	
46	Shriram Institute for Industrial Research, Delhi	Manish Rawat	Principal Member	2
47	Shriram Institute for Industrial Research, Delhi	Surabhi Gupta	Alternate Member	2
48	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	D S Nagesh	Principal Member	
49	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Shri. Vinodkumar V	Alternate Member	1
50	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Amrutha C	Alternate Member	
51	Terumo Penpol Private Limited, Thiruvananthapuram	Shri B. Harikrishanan	Alternate Member	2
52	Terumo Penpol Private Limited, Thiruvananthapuram	Manoj A.	Principal Member	2
53	Thermo Fisher Scientific India Private Limited, Mumbai	Vijay Kumar	Principal Member	2

54	Thermo Fisher Scientific India	Manish Shanghai	Alternate	
	Private Limited, Mumbai	Wallish Shanghai	Member	
55	Thermo Fisher Scientific India	Shri Ghosh	Young	
	Private Limited, Mumbai	Debjyoti	Professional	
	University College of Medical		Principal Member	
56	Sciences and Guru Teg Bahadur	Mrinalini Kotru		
	Hospital, New Delhi			
	University College of Medical		Alternate	
57	Sciences and Guru Teg Bahadur	Rajarshi Kar		2
	Hospital, New Delhi		Wieniber	
	University College of Medical		Vouna	
58	Sciences and Guru Teg Bahadur	Charu Jain	Drofossional	
	Hospital, New Delhi		Professional	
	Vardhman Mahavir Medical		Principal Mambar	
59	College and Safdarjung	Rajni Dawar		2
	Hospital, New Delhi		Wieniber	
60	Voluntary Organisation in		Dringingl	
	Interest of Consumer Education	M. A. U. Khan	Member	
	(VOICE), New Delhi			3
61	Voluntary Organisation in	DV	Alternote	5
	Interest of Consumer Education	D. N. Mukhonodhyoy	Member	
	(VOICE), New Delhi	wiuknopadnyay		

Annexure 2

DOC NO: IS 4381 TITLE : Specification of Pathological Microscope NAME OF THE ORGANIZATION: **Magnus Opto Systems India Pvt. Ltd**.

Sl.	Clause/Sub-	Commentator/	Type of	Justification	Proposed change
No.	clause/	Organization/	Comments		
	para/table/fig.	Abbreviation			
	No.				
	commented				
		Magnus	Technical	It is mentioned	The reference should
1				that it is for	be revised for
	IS 4381 CL			monocular only	monocular,binocular &
	No 1.1			but it's a standard	trinocular instead of
	(Scope)			for pathological	only monocular
				microscope, so it	
				may be binocular	
				and Trinocular	
				too. We need to	
				apply for IS 8275	
				separately for	
				binocular	
2		Magnus	Technical	The fine motion	The reference may be
	IS 4381 CL			should be 0.2mm	removed and replaced
	No 5.2			or 0.3 mm per	as proposed.
				revolution as per	
				the design. In this	
				category of	
				microscope	
				0.1mm does not	
				exist.	

Annexure 3

DOC NO: IS 7183 - 1973 TITLE: Specification for Flask, Culture, Haffkine NAME OF THE COMMENTATOR/ORGANIZATION: Satish Chitriv (Borosil Limted)

	Clause/Sub-	Type of Comments		
S1.	clause/	(General(ge)/	T (C' (C' st	
No.	para/table/fig.	Editorial(ed)/	Justification*	Proposed change*
	No. commented	Technical(<i>te</i>))		
1	1	Technical	Customers are using 3L	New addition of 3L
			Haffkine flasks too for	capacity
			preparation of culture in	
			nutrient media and Borosil	
			& other laboratory	
			glassware manufacturer in	
			India	
2	2	Technical	3.3 Borosilicate glass is	Material should be 3.3
			generally used for all type	Borosilicate glass
			of laboratory glassware	instead of neutral glass
			manufacturing by all	
			laboratory glassware	
			manufacturer in India	
3	3	Technical	Due to addition of 3L	Fig. 1 to be replaced
			capacity	and table for
				dimensions of 3L & 4L
				capacity to be added
4	4.6	Technical	Due to addition of 3L	Need to add capacity of
			capacity	3L flask upto the neck
				like 4L capacity in the
				existing standard.
5	5.3	Technical	It is a standard and	Autoclaving
			recommended autoclave	temperature at 121 °C
			temperature.	to be added as a process
				parameter

Table 1

Capacity	Total Height	Body Diameter	Bae Diameter	Neck Height	Neck OD at	Neck OD at	Neck Wall thickness	Body wall thickness (t1)
	(H)	(D)	(D1)	(h)	top	bottom	(t)	
					(D2)	(D)		
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

Annexure 4

TITLE: Specification for Tube, Culture, Screw Cap NAME OF THE COMMENTATOR/ORGANIZATION: Satish Chitriv (Borosil Limted)

Sl. No.	Clause/Sub- clause/ para/table/fi g. No. commented	Type of Comments (General(ge)/ Editorial(ed)/ Technical(te))	Justification*	Proposed change*	
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 36	