BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Medical Laboratory Instruments Sectional Committee (MHD 10)	23	11:00 AM, 12 November 2024, Tuesday

Mode: Hybrid

Link: https://bismanak.webex.com/bismanak/j.php?MTID=ma84b68c28e239e4d51eb41de4ea7944e

Meeting number: 2517 305 6793

Password: MHD10@23 (64310123 when dialling from a video system)

Venue: L C Verma Hall, BIS Manak Bhawan, 9, Bahadur Shah Zafar Marg, New Delhi, Delhi 110002

Chairperson	**Dr. Sudip Kumar Datta** Additional Professor and Head, Department of Laboratory Medicine, AIIMS, New Delhi
Member Secretary	Mr. Pawan Kumar Scientist B/Assistant Director, MHD, Bureau of Indian Standards

ITEM 0 GENERAL

0.1 Welcome Address by BIS

0.2 Opening Remarks by Head (MHD)

0.3 Opening Remarks by CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 22st meeting of Medical Laboratory Instruments Sectional Committee (MHD 10) held on 12 July 2024 approved by the Chairperson was circulated to all members through BIS portal as well as email dated 11 August 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.

2.1.1 In the earlier meeting the committee constituted a working group for updating the scope of MHD 10. The rationale for updating of the scope is enclosed at ***Annexure 1.*** The recommendations of the working group will be presented to the committee. The said working group consisted of the following members:

Sr. No.	Organization	Representative
1	All India Institute of Medical Sciences, New Delhi	Dr. Sudip Kumar Datta
2	Bharati Vidyapeeth Medical College, Pune	Col Mahadevan Kumar
3	CSIR - Central Scientific Instruments Organisation, Chandigarh	Dr. Neelesh Kumar
4	National Centre for Disease Control, New Delhi	Dr. Monil Singhai

2.1.2 **Formation of panels under MHD 10:**

As communicated to the members regarding the creation of Panels under MHD 10 Sectional Committee, the following working panels are created under the MHD 10 sectional committee:

1. **PANEL 1 - Laboratory glassware and plasticware:** To coordinate the standardization of products related to glassware and plasticware e.g. pipettes, glass tubes for pathology work, swab tubes, flasks, bottles etc.
2. **PANEL 2 - Equipment for processing, handling and preparation of samples:** To coordinate the standardization of products used for processing, handling and preparation of samples e.g. laboratory centrifuge, mixer, shakers, stirrers, anaerobic workstation, laminar flow, biosafety cabinets etc.

The committee may discuss on convenorship and nominations in the above mentioned panels.

2.2 The present composition of Medical Laboratory Instruments Sectional Committee (MHD 10) along with participation status of members is enclosed at ***Annexure 2***.

2.3 The attendance of members in Sectional Committee meetings is essential for its efficient and effective functioning. Accordingly, any member remaining absent from two consecutive meetings and/or fifty percent or more meetings of the Sectional Committee in a year will become automatically disqualified to continue as the member of the Sectional Committee.

2.4 The following members were absent in the last meeting held on 12 July 2024 and follow-up was made with these members and the status is given below:

Sl. No.	Organisation	Nomination
1.	Directorate General of Health Services, New Delhi	*Confirmation received on their interest for participation in MHD 10*
2.	ICMR - National Institute of Cancer Prevention Research, Noida	*Confirmation received on their interest for participation in MHD 10*
3.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	*Confirmation received on their interest for participation in MHD 10*

The Committee may please note.

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-third of the committee composition, as far as possible.

The committee may please note and review the composition.

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 The following draft Indian Standards / Amendments have been sent for wide circulation:

Sl. No.	Document No.	Title	Last date for comments	Comments received (Yes/No)
1.	MHD/10/25168	Medical Laboratory Glassware Ostwald-Folin Type Pipettes Specification First Revision	03 Nov 2024	**No**
2.	MHD/10/25169	Medical Laboratory Glassware Roux Bacteriological Flask - Specification First Revision	03 Nov 2024	**No**
3	MHD/10/25170	Medical Laboratory Glassware Bijou bacteriological bottle - Specification First Revision	17 Oct 2024	**No**
4	MHD/10/25171	Medical Laboratory Glassware Culture tube with screw cap - Specification First Revision	05 Nov 2024	**No**
5	MHD/10/25174	Specification for thin-walled glass capillary pipettes	*Last date not over*	**No**
6	IS 7183 : 1973	Specification for flask, culture, haffkine	*Last date not over*	**No**
7	MHD/10/25173	Specification for tube, haemometer	*Last date not over*	**No**

8	MHD/10/25172	Specification for anaerobic jar	*To be circulated*	**No**
9	IS 3742 : 1990	Medical glass instruments - Pipettes, dilution for haemocytometers specification (Second Revision)	*To be circulated*	**No**
10	IS 4067 : 1967	Specification for tube, swab (West Type), for throat	*To be circulated*	**No**

3.2 The documents where no comments have been received may be taken up for finalization.

The Committee may kindly deliberate.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 There are no draft Indian Standards/amendments for wide circulation

The Committee may kindly approve.

4.2 The comments on WC drafts shall be made only through the Standardization Portal. The BIS portal provides a very user friendly interface and helps faster compilation and analysis of comments. In case of any difficulties in accessing the portal, the members may contact the Member Secretary for necessary guidance.
The Committee may kindly note.

ITEM 5 DRAFT UNDER PREPARATION

5.1 The following indigenous subject drafts are under preparation.

Sl. No.	Project Title.
1.	Vortex Mixer
2.	LBC (liquid-based cytology) brush
3.	Lab plasticware - filter tips for standard pipettes
4.	Multiprobe Ultrsonicator
5.	Clinical centrifuges
6.	Gradient thermocycler
7.	Platelet Incubator with Agitator
8.	Anaerobic Workstation
9.	Double Beam UV Spectrophotometer
10.	HPLC System specifications
11.	GC-MS SQD with Liquid Autosampler and Headspace
12.	Quaternary FHPLC

The Committee may kindly note.

5.2 **Commenting on P-Drafts by Members of Technical Committee**

5.2.1 P-Draft is the stage where members of the concerned technical committee can support or reject the project or offer comments for improvement. Therefore, abstaining from commenting on the P-Draft by a member has serious implications on the quality of the draft. BIS had issued directions regarding commenting on P-Drafts wherein any member not commenting on two consecutive and/or one-fourth of the P-Drafts circulated by the Technical Committee in a year will automatically be disqualified to continue as a member.

5.2.2 The members may examine the P-Draft document(s) whenever under circulation and offer comments as per the following options:

(a) Agree
(b) Agree (with comments*)
(c) Don't agree (with comments*)
(d) No Comments, as it is not related to my area of expertise.

5.2.3 The comments on P- Drafts shall be made only through the Standardization Portal.

The Committee may kindly note.

5.3 ***Research and development Project Allotted:***
With reference to the R&D project of MHD 10 on study of Vortex mixers (MHD 0162), based on the evaluation of proposals received, the research evaluation committee approved and allotted to with following details:

Project Code	**Project Title**	**Proposer details**	**Approved Project cost (in Lakh Rs.)**
MHD 0162	Study of Vortex Mixers specifications	Dr Rajesh Singla, NIT Jalandhar	2.1416

Further details and the first report of the project are attached at Annexure 3.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 No comments have been received on published Indian Standards.

The committee may kindly note.

ITEM 7 NEW SUBJECTS

7.1 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.

7.2 As part of implementation of National Medical Devices Policy, 2023, NITI Aayog directed Department of Pharmaceuticals (DoP) to prioritize the List of Medical Devices for setting of Indian Standards. Based on the deliberations held in the series of meetings convened by DoP in which MoH&FW, DGHS, ICMR, CDSCO, BIS, AMTZ a final lists of 417 medical devices was provided by DoP to BIS in September 2024. BIS has mapped the

available Indian Standard against the finalized list. From the final analysis of the consolidated list the following medical devices were allotted to MHD 10:

Sr. No.	Sr. No. in Master	Applicable product standards as per CDSCO	Other applicable standards as per CDSCO	CII remarks	Target	Status
1	Automatic Anaerobic Jar System	Manufacturer's validated standards	ISO 14971; EN 13612; EN 13640; EN 61010-1; EN 61010-2-101		**March 2025**	Subject already approved under MHD 10
2	Fully automated Liquid based cytology system	IEC 61010-2-081	EN ISO 13612; EN ISO 14971; IEC 61326-1; IEC 61326-2-6; IEC 61010-1; IEC 61010-2-010; IEC 61010-2-101; IEC 62304; IEC 62366;		**December 2025**	Subject already approved under MHD 10
3	Osmometer	Manufacturer's validated standards	EN ISO 14971; IEC 61010-1/AMD1; IEC 61010-2-101; EN 61326-1;		**August 2025**	Subject already approved under MHD 10
4	Semenology incubator	Manufacturer's validated standards	IS EN 556-1; IS EN 60601-1; IS EN 60601-1-6; IS EN 60601-1-2; IS EN 62366-1; BS EN 62304		**December 2025**	
5	PCR/Thermal Cycler/Real time PCR/ Digital PCR/Real time quantitative PCR	Manufacturer's validated standards	EN ISO 14971; EN 61010-1 + A1; EN 61010-2-101; IEC 61010-2-010; EN 61326-1; EN 61326-2-6; ISO 20916; EN 13612; EN 62366-1; 80/181/EEC; EN 62304	ISO 15223-1:2021 ISO 18113-1:2011 ISO 18113-3:2011 IEC 60601 IEC 62304:2006	**December 2025**	Subject already approved under MHD 10

BIS has taken up formulation of standards for these 214 devices on priority and the work is expected to be completed in phased manner by December 2025.

The Committee may kindly deliberate.

ITEM 8 TECHNICAL ISSUES

8.1 There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in ISO/IEC

9.1.1 BIS participates in the International Standardization activities of the International Organization for Standardization (ISO) thereby contributing to International Standards development activities. It is a constant endeavor of the Sectional Committees to identify priority areas for participation in International technical committees that are of strategic importance to India and to identify relevant experts who would actively contribute to international standardization.

9.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and other documents circulated by ISO seeking votes/comments. The members should carefully examine the documents taking into consideration nation's interests and send the comments to BIS keeping in mind that if these ISO Standards so finalized are adopted as Indian Standards in future, the Indian Medical Device Industry would not have any problem in its implementation. The experts who are not contributing to international standardization by submitting comments/feedback on work items and ballots will not be allowed to represent BIS (India) in ISO/ IEC Technical meetings.

The Committee may kindly note.

9.2 Participation of Working Group Experts in ISO Technical Committees

9.2.1 Working Groups (WGs) are established by ISO/IEC Technical Committees for specific tasks. The Experts are nominated in these WGs by BIS ('P' Member National Standards Body – NSB) to deal with specific tasks allocated to the Working Group. Persistently Inactive Experts, meaning the absence of contributions through attendance to WG meetings or by correspondence, will be removed from the Working Groups by ISO Technical Committee. This removal of Inactive Experts would also reflect badly on the 'P' Member NSB. Therefore, participation of nominated Indian Experts at the Working Group level of ISO is of critical importance while being a part of BIS for Standards Development.

9.2.3 The nomination of above members as 'Expert' to ISO Working Groups has been considered by BIS based on the recommendations of the Sectional Committee taking into account that he/she would actively participate in the projects concerned. By accepting an appointment as an Expert, the respective members are committing to actively participate in the Working Group to which he/she is appointed and to fulfill the obligations associated with participation. The Working Group Experts are also required to inform the National Mirror Committee (i.e the concerned BIS Technical Committee that has the liaison with the ISO Technical Committee) of their contribution and progress of the work. The level of contribution of the nominated Working Group Experts may be reviewed and decision may be taken regarding continuation/ termination of nomination.

The Committee may kindly consider.

9.3 Identification of Working Group Experts in ISO Technical Committees

9.3.1 India (BIS) is not participating in the following Working Groups of ISO as no Experts have been nominated by BIS in these WGs:

Sl. No.	Working Group Number/ Title
1.	ISO/TC 48/WG 3 Microfluidic Devices
2.	ISO/TC 48/WG 7 Volumetric apparatus made of glass and plastic
3.	ISO/TC 48/WG 4 Liquid Handling Devices – Manual and Semi-Automatic
4.	ISO/TC 48/WG 5 Liquid Handling Devices- Automatic
5.	ISO/TC 48/WG 6 Non-volumetric glass and plastic ware

9.3.2 The Organizations / Members may propose for nomination of experts in the above WGs considering the following:

a. The knowledge and expertise of the expert in the subject area.

b. The willingness of the member to fulfill the responsibilities and expectations and commitment to devote ample time for international standardization activities.

The Committee may kindly consider.

9.4 Harmonization of Indian Standards with International Standards

9.4.1 ISO comprising of global experts on various subjects regularly bring out International Standards. The Sectional Committees on a regular basis needs to review the ISO Standards published against the existing National Standards, current trade practices, consumer expectations, global trends, etc and decide for review of the published National Standards. In the process, Sectional Committees after a close scrutiny of the ISO Standards, may decide on adoption/adaptation of the ISO Standards keeping in view the technical relevance of the subject to the national conditions. Harmonization is not undertaken in case the ISO Standards are not relevant to Indian conditions or would put the Indian industry at disadvantage. The Sectional Committees while reviewing such ISO Standards also explore the possibility of adopting such ISO Standards on which no Indian Standards exist.

The Committee may kindly deliberate and recommend the Standards to be adopted as Indian Standards.

ITEM 10. PROGRAMME OF WORK

10.1 The present Programme of Work of Medical Laboratory Instruments Sectional Committee (MHD 10) is available at BIS website www.bis.gov.in.

The Committee may kindly note.

10.2 The progress of development of Indian Standards at various stages is given below:

Stage	No. of Documents
Under Print	0
Under Development	13

ITEM 11. REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

11.1.1 All Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archiving in the light of technological developments that have happened so far in relation to these standards. This exercise has to be completed in a time bound manner. The details in this regard are given below:

Total as per PoW	**Under Development**	**Under Print**	**Remaining**	**Under Progress (out of the remaining)**	**Pending**
21	10	2	8 (out of which 5 recommended for withdrawal)	3	1 (Adopted standard not revised by ISO)

The Committee may kindly review.

11.1.2 In the 21st meeting of MHD 10, a working group was formed to review and resolve comment received on IS 4381 Specification of Pathological Microscope. A consultative meeting was held on 21 October 2024 in this regard and the recommendation of the meeting are attached to Annexure 4.

11.2 Review of Standards as per 5-year cycle

11.2.1 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.

11.2.2 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.

The Committee may kindly deliberate and decide further course of action.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

12.1 There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 13 DATE AND PLACE OF NEXT MEETING

13.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 10 is scheduled for Tuesday, February 04, 2025.

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

Annexure 1

Rational for scope updation:

BIS as National Standard body mandates to formulate standards for all consumer products which may directly or indirectly affect consumers in terms of quality, safety and efficacy.

Gap area: There are around 400 sectional committees in BIS. The standards of laboratory products (medical and non-medical) are covered by following committees:

CHD 10: Deals with laboratory glassware and plastic ware

MHD 10: (as per current scope) Laboratory glassware and plasticware used in Medical Laboratories

MHD 19: Deals with IVDs, analysers (products which provides clinical investigation results)

MHD 20: Subjects dealing with processing of samples with biotechnology methods (e.g. DNA sequencing etc.)

MHD 14: Laboratory quality management systems.

The following instruments which are extensively used in Medical Laboratories should be covered by MHD 10 but is ***not covered by any committee of BIS***:

- Processing instruments: Sample mixers, shakers, rotors, rockers, stirrers, Pipette control, microtomes
- Cabinets: Incubators, Biosafety cabinets, Anaerobic workstations, Water baths
- Chromatographs etc.

Therefore, the scope of MHD 10 needs to be revised to bridge this gap.

Current scope of MHD 10: 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.

Scopes of related committees:

CHD 10 Scope: To formulate Indian Standards for terminology, code of practice, methods of sampling and tests and specifications for glass including, its raw material, glassware, processed glass, electrical and electronic visual displays, laboratory ware, including thermometer, hydrometers (made from glass, plastics, ceramic, silica etc) not covered in scope of other Sectional Committees.

MHD 14 Scope:

a) To prepare codes, guides and standards (physical, staff and equipment planning), quality management systems and operational systems for health care services;

b) Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance.

MHD 19 Scope: To formulate Indian Standards on:

a) In-vitro Diagnostic kits, reagents, analyzers and associated software

b) Biological and clinical evaluation of medical and dental materials, devices, implants together with standardization of biological test methods applicable to those materials and devices, and c) Good clinical

practice principles to clinical investigations in humans of those devices.

MHD 20 Scope:

a) Standardization in the field of medical biotechnology, including but not limited to Biobanks and Bioresources, analytical methods (including Chemical and Biological), products (including tissue-engineered medical products), delivery systems, etc.

b) Standardization in the field of medical nanotechnology, including but not limited to products, processes and test methods.

Draft Scope:

a) To formulate Indian Standards on products used in medical laboratory for collection, preparation, handling, processing of samples.
b) Excluding products giving clinical/diagnostic data, biotech products/ processes/ services.

Annexure 2

Composition and participation Sectional Committee (MHD 10)

Sr. No.	Organization	Category	Primary Member	Alternate Member	Attendance
1	All India Institute of Medical Sciences, New Delhi	Academic Institution	Dr. Sudip Kumar Datta	Dr Tushar Sehgal	2
2	All India Institute of Medical Sciences, Mangalagiri	Academic Institution	Dr. Desai Vidya Sripad	Dr. Nichenametla Gautam, Dr. Sumit Rai	2
3	Association of Indian Medical Device Industry, New Delhi	Industry Association	Shri Manish Airan	Shri C.S.Prasad	2
4	Bharati Vidyapeeth Medical College, Pune	Academic Institution	Col Mahadevan Kumar	Dr Meghana Khandu Padwal	2
5	Borosil Glass Works Limited, Mumbai	Industry	Shri Jeevan Dogra	Shri Satish Chitriv	1
6	CSIR - National Physical Laboratory, New Delhi	R&D Organization	Dr. G. Sumana	Dr Tuhin Kumar Mandal, Dr Rajesh	2
7	CSIR - Central Scientific Instruments Organisation, Chandigarh	R&D Organization	Dr. Neelesh Kumar	Dr Sanjeev Soni	2
8	Directorate General of Health Services, New Delhi	Central Ministry/Dept.	Dr. Naresh Panchal	Dr. B.S Charan	1
9	Dr D. Y. Patil Medical College, Hospital and Research Centre, Pune	Academic Institution	Dr. Chandrashekhar G Raut		2
10	Dr Ram Manohar Lohia Hospital, New Delhi	Academic Institution	Prof. Dr. Arvind Ahuja	Dr Saswati Das, Dr Arvind Kumar Achra	2
11	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Industry	Shri Praveen Kumar Sharma	Shri Upinder Vishen	2

12	ICMR - National Institute of Cancer Prevention Research, Noida	R&D Organization	Dr. Ruchika Gupta		1
13	ICMR - National Institute of Immunohaematology, Mumbai	R&D Organization	Dr. Bipin Prakash Kulkarni	Dr. Anindita Banerjee, Dr. Umair Bargir	2
14	Indian Council of Medical Research, New Delhi	R&D Organization	Dr. Suchita Markan	Dr Deepak Gupta	2
15	Kalam Institute of Health Technology, Vishakhapatnam	R&D Organization	Shri Suraj Suresh Naik	Ms. Sruthi Saladula, Mr.Pramod	2
16	Magnus Opto Systems India Private Limited, New Delhi	Industry	Shri Harmeet Singh Ahuja	Shri Deepak Yadav	1
17	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Regulatory Body	Dr. Gayathri S	Shri Ashok Kumar	2
18	National Centre for Disease Control, New Delhi	R&D Organization	Dr. MONIL SINGHI	Dr. Shubha Garg	2
19	Post Graduate Institute of Medical Education and Research, Chandigarh	Academic Institution	Prof Bikash medhi		1
20	Remi Elektrotechnik Limited, Mumbai	Industry	Shri Sunil Saraf	Shri Suhas Kulkarni, Shri Manoj Kumar Yadav	2
21	Schott Glass India Private Limited, Jambusar	Industry	Shri Anand Bakshi	Shri Lalatendu Behera	2
22	Shriram Institute for Industrial Research, Delhi	R&D Organization	Shri Manish Rawat	Dr Surabhi Gupta	2
23	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	R&D Organization	Shri D S Nagesh	Ms. Amrutha C, Shri. Vinodkumar V	1
24	Terumo Penpol Private Limited, Thiruvananthapuram	Industry	Shri Manoj A.	Shri B. Harikrishanan	2

25	Thermo Fisher Scientific India Private Limited, Mumbai	Industry	Shri Vijay Kumar	Shri Manish Shanghai, Shri Ghosh Debjyoti	1
26	University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi	Academic Institution	Dr Mrinalini Kotru	Dr Rajarshi Kar, Dr Charu Jain	2
27	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Academic Institution	Dr. Rajni Dawar	Dr Deepa Haldar	2
28	Voluntary Organisation in Interest of Consumer Education (VOICE), New Delhi	Consumer Group	Shri M. A. U. Khan	Shri B. K. Mukhopadhyay	2

Annexure 2

Details of allotted research project (MHD 10)

TC	Project Code	Title of the project	Proposer name and designation	Estimated expenses (Total and breakup)	Duration of project	Date of award	Date of Release of 1st Instalment	Date of commencement of project	Deadline for Final Project report
MHD 10	MHD 0162	Study of Vortex Mixer specifications	Dr Rajesh Singla NIT Jalandhar	Total Project cost: 214160 Manpower cost: 20,000 per month (1,20,000) Consumables: 10,000 Equipment: 14,160 Travel: 50,000, Any other/Overhead expenses: 20,000	6 Month	27-Sep-24	Date of Transaction: 27 September, 2024 Fund Release Amount: 57823/-	27-Sep-24	Thursday, 27 March 2025

Planned Meeting progress review

Sr. No.	Meeting Date	Meeting Time	Discussion points
1	06 Sep 2024	12:00 PM	- First interaction with the proposers. - Status of submission of consent form as well as updates on 1st instalment
2	25 Oct 2024	12:00 PM	Discussed the objectives, expectations, timelines and final deliverables of the project
3	12 Nov 2024	11:00 AM	
4	29 Nov 2024	12:00 PM	
5	13 Dec 2024	12:00 PM	
6	27 Dec 2024	12:00 PM	
7	10 Jan 2025	12:00 PM	

8	24 Jan 2025	12:00 PM	
9	14 Feb 2025	12:00 PM	
10	28 Feb 2025	12:00 PM	
11	14 Mar 2025	12:00 PM	
12	21 Mar 2025	12:00 PM	

Progress reports on R&D project:

Progress report Month 1	**Literature review:** Identification of essential principles of vortex mixer, any existing regional or international standards on vortex mixers **Desktop research:** List of indigenous manufacturers, import **Sampling plan:** Tentative plan to visit manufacturing sites, testing laboratories	Tuesday, 12 November 2024	**Submitted**
Progress report Month 2		Friday, 29 November 2024	Yet to submit
Progress report Month 3		Friday, 27 December 2024	Yet to submit
Progress report Month 4		Friday, 31 January 2025	Yet to submit
Progress report Month 5		Friday, 28 February 2025	Yet to submit
Final project report		Friday, 21 March 2025	Yet to submit

1st Progress report

Vortex Mixer

Vortex Mixture

A vortex mixture is a type of fluid flow system where different substances or phases (such as liquids or gases) are blended together using the vortex effect, which is a swirling, spiralling motion. This effect occurs when fluids are rotated rapidly, creating a central area of low pressure and causing the substances to mix thoroughly.

In a vortex mixer, which is commonly used in laboratories, the rapid circular motion facilitates uniform mixing of samples. The vortex action helps in blending materials at a microscopic level, making it useful for scientific and industrial processes where thorough mixing of components is essential. The main advantage of vortex mixing is its efficiency in creating homogeneous mixtures quickly, making it widely applicable in fields like chemistry, biology, and chemical engineering.

Types of Vortex Mixers:

1. Variable Speed Vortex Mixers

Variable speed vortex mixers allow users to adjust the mixing speed to suit different applications. Higher speeds can be applied for intense agitation, while lower speeds are suitable for gentler mixing, providing versatility for handling various sample types.

2. Fixed-Speed Vortex Mixers

These mixers start operating at a fixed speed when the head is pressed down, delivering full RPM for strong vortexing. They are straightforward and ideal for applications that require consistent, powerful mixing.

3. Digital Vortex Mixers

Digital vortex mixers come with precise control features, including options for continuous or pulse mixing, along with a digital display for speed and time. With speeds ranging from 300 to 4,200 RPM, they can handle both high-intensity and low-speed mixing. Available accessories may include platforms for flasks, inserts for microtubes, and microplate holders.

4. Analog Vortex Mixers

Analog vortex mixers offer manual adjustment options, allowing users to set a low speed for gentle shaking or a high speed for more vigorous mixing. They can operate in touch mode, activated by pressing the cup head, or in continuous mode for prolonged mixing with additional accessories.

5. Mini Vortex Mixers

Compact and portable, mini vortex mixers are designed for test tubes and come with a suction base to enhance stability and reduce noise. Mixing starts when a test tube is pressed into the attachment and stops automatically when it's removed. With a footprint of 100 mm by 100 mm, they reach speeds up to 4,500 RPM.

6. Multi-Tube Vortex Mixers

Multi-tube vortex mixers allow simultaneous mixing of multiple tubes or flasks, which is especially useful for labs handling larger sample volumes. Operating speeds range from 300 to 2,500 RPM, and attachments include tube foam and flask foam to hold samples securely.

7. Pulsing Vortex Mixers

Ideal for applications such as cell disruption, pulsing vortex mixers use intense pulsing actions to disrupt cells in glass bead treatments effectively. This pulsing action minimizes heat while maximizing mixing efficiency. They typically include a holder for micro-centrifuge tubes of 0.5 mL or 2.0 mL.

8. Microplate Vortex Mixers

Designed for mixing microplates, these mixers can handle various speeds to meet different experimental requirements. Non-digital, variable speed models offer a cost-effective option for labs needing reliable performance without digital displays, making them ideal for routine lab applications.

Vortex mixers operating Principles

The main principles involved include:

1. **Rotational Motion:**
   The mixer uses a rotating platform or head, which generates a circular motion. This motion helps to produce a vortex within the liquid, mixing the contents evenly and rapidly.

2. **Oscillatory or Pulsing Action:**
   Some vortex mixers are designed to pulse, which can enhance the mixing process by preventing excessive heat buildup. This is especially beneficial for sensitive samples like biological or chemical reagents.

3. **Adjustable Speed:**
   Many vortex mixers allow users to control the mixing speed, which provides flexibility for mixing various types of samples. Higher speeds are typically used for thicker or denser liquids, while lower speeds are ideal for delicate mixtures.

These principles are what make vortex mixers indispensable in laboratories for tasks like mixing cell cultures, preparing reagents for chemical reactions, and other applications where uniform mixing is crucial.

Effects of These Principles

The effects of these principles are significant in the mixing process, contributing to the efficiency and effectiveness of vortex mixers:

Enhanced Mixing:

The combination of centrifugal and rotational forces leads to rapid and consistent mixing, ensuring even distribution of components in the sample.

Flexibility:

With adjustable speeds, users can select the optimal mixing intensity for different types of samples, from gentle shaking to vigorous vortexing.

Reduced Heat Generation:

In some mixers, the pulsing action helps reduce heat build-up, making it ideal for temperature-sensitive samples.

Consistency: The irregular motion created by the eccentric shaft ensures that the mixing process is thorough and that sample components are uniformly blended.

Literature Review on Vortex Mixers

Introduction to Vortex Mixers

A vortex mixer is an essential laboratory tool designed to rapidly agitate liquid samples, creating a vortex effect to ensure thorough mixing. This device is commonly used in scientific fields such as biology, chemistry, and pharmaceuticals, where accurate and efficient mixing of reagents is crucial. The mixer works by generating a circular motion in the sample using centrifugal or rotational forces, ensuring uniform distribution of the components within the liquid.

Parts of a Vortex Mixer

The vortex mixer consists of several critical components that work together to achieve effective mixing:

1. Motor: The motor drives the mixing process, providing the power to rotate the mixing head.

2. Mixing Head (Rubber Cup): The rubber cup oscillates in circular motion, which creates the vortex. This is the primary part responsible for agitating the liquid sample.

3. Sample Holder: This is the part where the samples are placed. The holder secures the sample in place, ensuring stability during mixing.

4. Eccentric Shaft: In some vortex mixers, the shaft is slightly off-center, which creates an eccentric motion that further disrupts aggregates in the sample, ensuring thorough mixing.

5. Control Panel: The control panel allows the user to adjust the speed and operational modes of the mixer, providing flexibility depending on the type of sample being mixed.

6. Power Supply: This provides the necessary electrical energy to the motor and other components of the vortex mixer.

Regional and International Standards

Standards for vortex mixers in laboratories are not as universally regulated as those for medical or environmental devices, yet there are essential guidelines from various regions and organizations focused on performance, safety, and quality.

1. **International Standards:**
   Commonly adopted in the industry, ISO standards related to laboratory equipment can apply to vortex mixers. While there is no ISO specifically for vortex mixers, many labs follow standards on laboratory safety (ISO 15190) and quality control, ensuring mixers meet basic safety and performance benchmarks. Some equipment suppliers also comply with ISO 9001, which addresses quality management systems and is indirectly relevant to vortex mixer quality.

2. **European Standards:**
   The European market has strict quality and safety standards due to regulations from entities like the European Committee for Standardization (CEN). The CE marking, for instance, certifies compliance with health, safety, and environmental protection standards for products sold within the European Economic Area, which vortex mixers commonly adhere to. Additionally, the region emphasizes eco-friendly practices, pushing manufacturers to prioritize energy efficiency and sustainability in design.

3. **Regional Variations:**
   Standards for vortex mixers vary by region, with North America emphasizing safety and reliability, governed by agencies such as Underwriters Laboratories (UL). In contrast, the Asia-Pacific region, with high demand for laboratory equipment due to growing biotech industries, has a mix of local and international standards and often requires customization for regional compliance.

4. **Industry Compliance and Certification**:
   Prominent manufacturers like Thermo Fisher Scientific and VELP Scientifica also ensure that their products align with general international standards and may offer optional calibration and certification for specific laboratory requirements. These certifications aren’t always mandated but help labs maintain high levels of accuracy and performance.

For detailed and specific compliance, manufacturers often provide product certification and alignment documentation to assist labs in meeting any regulatory requirements. Vortex mixers with compliance certificates or quality management certifications ensure their usability across different regions' safety and quality standards.

ISO Standards for Laboratory

Equipment:

ISO 8655:

This standard covers the performance and testing requirements for laboratory glassware and equipment, including pipettes and dispensers, which may indirectly impact the use of vortex mixers.

ISO 15189:

Relevant if the vortex mixer is used in a clinical or medical laboratory setting. It covers the general requirements for the competence of medical laboratories and includes equipment calibration, safety, and reliability.

2. IEC (International Electrotechnical Commission) Standards:

IEC 61010-1: This standard is for the safety of electrical laboratory equipment, including vortex mixers. It covers the design and construction requirements to ensure the equipment operates safely under expected conditions, including protection from electrical hazards and mechanical failures. IEC 61326-1: Pertains to the electromagnetic compatibility (EMC) of laboratory equipment, including vortex mixers, ensuring that the equipment doesn't interfere with other devices in the laboratory.

3. ASTM Standards:

While there isn't a specific ASTM standard for vortex mixers, ASTM standards often cover the performance of laboratory equipment. For example:

ASTM E287-13: Covers methods for evaluating the accuracy of laboratory equipment and could apply if the vortex mixer is used in experimental or testing procedures.

4. Safety Standards:

UL (Underwriters Laboratories)

UL standards are widely recognized for safety certification in the United States. Many vortex mixers are tested according to UL standards for electrical safety, such as UL 61010-1 (similar to IEC 61010-1 but specific to North America).

OSHA (Occupational Safety and Health Administration):

For vortex mixers used in industrial or laboratory settings in the U.S., OSHA guidelines might apply to ensure the safe operation of such equipment, including requirements for protective features, labeling, and training.

5. CE Marking (European Union):

In the European Union, products like vortex mixers must conform to the CE marking regulations, ensuring that the equipment complies with European safety, health, and environmental protection requirements. The CE marking is often required for electrical and laboratory equipment.

6. FDA (U.S. Food and Drug Administration) Regulations:

If the vortex mixer is used in pharmaceutical or food-related applications, the equipment may be subject to FDA regulations (under the Food, Drug, and Cosmetic Act or 21 CFR Part 820). The FDA may require documentation of equipment validation, calibration, and performance verification, especially in regulated environments.

7. Calibration and Performance

Standards: Vortex mixers, like other laboratory instruments, should be calibrated

according to established procedures, typically in compliance with ISO or ASTM guidelines, to ensure reproducibility and reliability in results. These standards may include checking parameters like speed range, mixing uniformity, and device stability.

Applications of Vortex Mixer

- It has wide application in the clinical and medical sectors for thawing and mixing samples.
- The vortexer has been used to suspend cell or tissue samples for use in tissue analysis and cell culture.
- When investigating proteins and enzymes, a vortex mixer is essential for the homogeneous mixing of samples with reagents and buffer.
- It is also utilized in heating and mixing samples in pharmaceutical areas.
- It is employed in schools and universities for practical demonstrations and experiments.
- Vortexer is used in quality control testing and sample preparation for industrial use.

Advantages of Vortex Mixer

- The various speed options guarantee that the intended speed is kept constant throughout the process.
- Depending on how many vials are being mixed at once, vortex mixers can hold one vial up to a dozen.
- Additionally, the vortex mixer works with minimal resources, expertise, and resources.
- The vortex mixer ensures an effective and dependable way of mixing samples.
- Limitations
- If the tube is held incorrectly, there is a chance of spilling.
- It does not apply when combining solid and liquid or solid and solid components.

Manufacturers

Vortex laboratory mixer Vornado™ (Manufacturer: Benchmark Scientific)

- It is a powerful mini vortexer that vortexes even the largest samples, such as 50 ml tubes. Thanks to its 4 mm orbit and fixed speed of 2800 rpm.
- Despite having a strong motor, the Vornado can fit on even the busiest bench thanks to its small footprint of fewer than 44 inches.
- The Vornado's distinctive head shape keeps liquids from getting into the housing, extending the motor's life.

Vortex mixer VMX-MT (Manufacturer: Bioevopeak)

- The VMX-MT Multi-Tube Vortexer uses brushless DC motor technology and microprocessor control.
- It can only process 50 samples at once at most.
- The mixing requirements of various test tubes can be met by choosing from a selection of test tube foams.

Vortex-Genie 2 (Manufacturer: Scientific Industries)

The U.S.-made Vortex-Genie 2 is a durable piece of scientific equipment thanks to its sturdy metal casing.

It includes three formats: analog speed control (Vortex Genie 2), digital time and speed control (Digital Vortex Genie 2), and analog time and speed control (Vortex Genie 2T).

Velp TX4 IR Vortex Mixer (Manufacturer: Carbon Scientific)

- It features a digital vibration time and speed control operating with a timer until 999:59 minutes.
- Presence of a multi-parameter display with a large, brilliant LCD.
- It offers maximum chemical resistance from technopolymer casing.

Fisherbrand™ Mini Vortex Mixer (Manufacturer: Fisher Scientific)

- The Fisherbrand™ Mini Vortex Mixer is a very small vortex mixer that rotates in a horizontal orbit.
- It accepts all sizes of tubes and containers.

Manufacturing And Trading Companies

1. **Remi Elektrotechnik Ltd.**

   Location: Mumbai, Maharashtra

2. **Medica Instrument Manufacturers Pvt. Ltd.**

   Location: New Delhi, India

3. **Scientech Technologies Pvt. Ltd.**

   Location: Jaipur, Rajasthan

4. **Borosil Scientific**

   Location: Mumbai, Maharashtra

5. **Lab Instruments (India)**

   Location: Mumbai, Maharashtra

6. **Bioneer India**

   Location: Hyderabad, Telangana

7. **Spectrum Scientific Instruments Pvt. Ltd.**

   Location: Pune, Maharashtra

8. **Pioneer Scientific Co.**

   Location: Ahmedabad, Gujarat

9. **Biotech International Ltd.**

   Location: New Delhi, India

10. **ACMAS Technologies Pvt.Ltd.**

    Location: Chennai, Tamil Nadu

11. **Thermo Fisher Scientific India**

    Location: Mumbai, Maharashtra (Also has locations in other major cities)

12. **Chadha Scientific Pvt. Ltd.**

    Location: New Delhi, India

13. **Elico Ltd.**

    Location: Hyderabad, Telangana

14. **Jain Scientific Suppliers**

    Location: Mumbai, Maharashtra

VISITS AND TENTATIVE PLANS FOR VISIT

1: iGene Labserve Private Limited (Gurugram ,Haryana)

Visited on 23/10/2024 at the assembling and calibration unit.

During my visit to the manufacturing unit, I was unable to collect data due to staff unavailability; however, I was able to discuss and gain insights into the assembly process.

Tentative Visit for data collection Second to third week of November 2024.

2: G.G. TECHNOLOGIES (Wazirpur , Delhi)

Tentative plan to visit in the month of December 2024

3: Bionics Scientific (a unit of Kartal Projects Pvt Ltd.)

Tentative Plan to visit in the month of December 2024.

Annexure 4

1st Consultative Meeting on the Revision of IS 4381- Pathological Microscope Standard

दिनांक तथा दिन **DATE & DAY**	21 October 2024, Monday
समय **TIME**	10:30 AM
स्थान **VENUE**	**Virtual**
संयोजक **CONVENER**	**Dr Sudip Kumar Datta** Addl. Professor and Head, Department of Laboratory Medicine, AIIMS, New Delhi

List of participants:

Sl. No.	**Name and organization**	**Role**
1)	Dr Sudip Kumar Datta, *Addl. Professor and Head, Department of Laboratory Medicine, AIIMS, New Delhi*	Convener
2)	Dr Ruchika Gupta, ICMR - National Institute of Cancer Prevention Research, Noida	Expert
3)	Mr. Pawan Kumar, *Scientist-B, MHD, Bureau of Indian Standards*	BIS representative
4)	Manoj Enterprises	Industry representative
5)	N.K. Jain Instruments Pvt. Ltd.	Industry representative
6)	Quality Scientific & Mechanical Works	Industry representative
7)	Scientific System	Industry representative
8)	Sudheer Scientific Works	Industry representative
9)	Micron Instrument Industries	Industry representative
10)	Unilab Microscope Mfg.Co.Pvt. Ltd.	Industry representative
11)	Micro Measures & Instruments	Industry representative
12)	Labex Kk International	Industry representative
13)	M.K.Optical Works	Industry representative
14)	Bl Scientific Instrument Co.	Industry representative
15)	Scientific India	Industry representative
16)	Lafco India Scientific Industries.	Industry representative
17)	Radical Scientific Equipments Pvt. Ltd.	Industry representative
18)	Magnus Opto Systems India Private Limited	Industry representative
19)	Bl Scientific Instrument Co.	Industry representative
20)	Scientific India	Industry representative
21)	Lafco India Scientific Industries.	Industry representative
22)	Radical Scientific Equipments Pvt. Ltd.	Industry representative
23)	Magnus Opto Systems India Private Limited	Industry representative

Discussions:

Mr. Pawan Kumar, Member Secretary, MHD 10 briefed the attendees about the objective of the meeting. BIS has received comments on IS 4381 and industry perspective was sought on the issue. The standard has 15 licensees and were invited to the meeting.

The following comment was received on IS 4381:

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
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.

Dr Ruchika Gupta, ICMR - NICPR, Noida mentioned that the above comments are contrary to each other and the standard has specifications for monocular microscope only and expanding the scope by removing monocular keyword from scope will extend require to add dimensions and other requirements of binocular and trinocular microscope.

Shri Harmeet Ahuja, Magnus Opto Systems India Private Limited mentioned that the standard may be improved by incorporating modern design and quality assurance requirements in the standard. This will ensure the quality and reliability of the licensed products.

It was also noted that BIS has the following standards on Microscope:

S.No.	IS No.	IS Title	TC	Aspect	Degree of Equivalence
1	IS 4381 : 1967 (Active)	Specification for pathological microscope	MHD 10	Product Specification	Indigenous
2	IS 7858 : 1991 (Active)	Surgical microscope - Specification (First Revision)	MHD 01	Product Specification	Indigenous
3	IS 3686 : 1966 (Active)	Specification for student - Type microscope	PGD 22	Product Specification	Indigenous
4	IS 5204 : 1969 (Active)	Specifiction for research microscope	PGD 22	Product Specification	Indigenous
5	IS 3081 : 1994 (Active)	Microscopes - General purposes - Dimensions and marking (First Revision)	PGD 22	Dimensions	Not Equivalent
6	IS 15269 : 2018 (Active)	Optics and optical instruments - Microscopes - Values, tolerances and symbols for magnification (First Revision)	PGD 39	Product Specification	Identical under dual numbering

Recommendations:

It was recommended that a by coordinating PGD department, a single standard on Microscope may be formulated incorporating modern design and quality assurance requirements in the standard. This will ensure the quality and reliability of the licensed products. If the same is not feasible, the current standard may be revised updating the requirements and expanding the scope.