भारतीय मानक Indian Standard

> चिकित्सा प्रयोगशाला हेतु काँच का सामान — हेमोग्लोबिनोमीटर के लिए पिपेट और जैव रासायनिक कार्य के लिए रक्त पिपेट — विशिष्टि (दूसरा पुनरीक्षण)

Medical Laboratory Glassware — Pipette for Haemoglobinometer and Blood Pipette for Biochemical Work — Specification

(Second Revision)

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January 2024

Price Group 5

Medical Laboratory Instruments Sectional Committee MHD 10

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standard, after the draft finalized by the Medical Laboratory Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

The first revision of this Indian Standard was published in 1980 with the title 'Specification for pipette for haemoglobinometer and blood pipette for biochemical work'. This revision has been brought out to align the cross-references to the latest editions and bring it in line with the current practices.

The composition of the Committee responsible for the formulation of this standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL LABORATORY GLASSWARE — PIPETTE FOR HAEMOGLOBINOMETER AND BLOOD PIPETTE FOR BIOCHEMICAL WORK — SPECIFICATION

(Second Revision)

1 SCOPE

This Indian Standard specifies requirements and methods of test for the following pipettes used in medical laboratories:

- a) Pipette for haemoglobinometer used in pathology work; and
- b) Blood pipette for biochemical work.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

IS No.	Title		
IS/ISO 718 : 1990	Laboratory glassware — Thermal shock and thermal shock endurance — Test methods		
IS 1382 : 1981	Glossary of terms relating to glass and glassware (first revision)		

3 TERMINOLOGY

For the purpose of this standard, the definitions given in IS 1382 shall apply.

4 MATERIAL

4.1 The pipettes shall be made from heat-resistant glass tubing or lead glass tubing, clear or with enamel back. The tubes shall have a uniform bore.

4.2 The mouthpiece shall be made of glass or suitable plastic.

4.3 The connecting tube shall be of rubber or polyethylene tubing, non-collapsible under suction by mouth.

5 SHAPE, DIMENSIONS AND CAPACITY

5.1 The shape and dimensions of the pipettes shall be as given in Fig. 1 to Fig. 3.

5.2 The pipette for haemoglobinometer shall be calibrated to contain 20 μ l up to the mark etched on it, at 27 °C.

5.3 The blood pipette shall be calibrated to contain 200 $^{\circ}$ C μ l at 27 $^{\circ}$ C.

5.4 The capacity of the pipette for haemoglobinometer at 27 °C up to the mark shall be 20 μ l ± 5 μ l and that of the blood pipette at 27 °C shall be 200 μ l ± 5 μ l up to the mark on it, when tested in accordance with the method specified in **8.1**.

6 WORKMANSHIP AND FINISH

The pipette shall be well-annealed and free from bubbles, blisters and, as far as possible, free from striae, stones and other visible defects. It shall be symmetrical about its axis. The bore of the pipette shall be uniform throughout. The capillary at the upper end of the pipette for haemoglobinometer may be expanded as shown in Fig. 2 or it may consist entirely of capillary bore. The top of the pipette shall be smooth and finished at right angles to the axis. The top 10 mm to 20 mm of the pipette may taper slightly to facilitate the attachment of a rubber tubing. The jet of the haemoglobinometer pipette shall be formed by grinding into a taper as shown in Fig. 2. The delivery jet of the blood pipette shall be made with a gradual taper. There shall be no sudden constriction of the bore at the orifice. The tapered portion shall be polished. The end of the jet shall be ground smooth and at right angles to the axis of the pipette. The jet of the blood pipette shall be beveled slightly at the periphery. The pipette shall pass the thermal shock test specified in 8.2.



FIG. 1 Assembly for Haemoglobinometer Pipette and Pipette for Biochemical Work with Details of MouthPiece



All dimensions in milimeters. FIG. 2 PIPETTE, HAEMOGLOBINOMETER





7 GRADUATIONS

The graduation lines shall be fine, clean, permanent and of uniform thickness and at right angles to the axis of the pipette. They shall be carried all-round the circumference of the pipette. On the haemoglobinometer pipette the mark 20 μ l shall be inscribed immediately above or below the line and shall be permanent. The blood pipette shall be marked at 100 μ l and 200 μ l, inscribed immediately above the respective line. When tested according to 8.3, there shall be no fading of the graduation lines or marks.

8 TESTS

8.1 Method for Determination of Capacity

The pipette shall be cleaned thoroughly and dried in an air oven maintained at 110 °C \pm 5 °C. It shall be cooled in a desiccator. The connecting tube and mouthpiece shall be attached. Mercury shall be sucked in and its level adjusted up to the graduation mark to be tested. This mercury shall be transferred into a clean and dry, previously massed, beaker or any other vessel and massed. The volume at 27 °C shall be calculated from the mass of the mercury determined.

8.2 Thermal Shock Test

Thermal shock test shall be in accordance with IS/ISO 718.

8.3 Test for Permanency of Marking

The pipette shall be completely immersed in a glass cylinder containing hydrochloric acid solution in distilled water of 0.01 normality. The cylinder and its contents shall be autoclaved at 98.1 kN/m^2 at 120 °C for 30 minutes. The autoclaving shall be repeated after allowing sufficient time for the cylinder and contents to come to room temperature. The markings shall not show appreciable reduction in intensity.

9 MARKING

9.1 The pipette shall be marked with the following:

- a) Name of the manufacturer;
- b) Symbol '27 °C' to indicate that the pipette is calibrated at 27 °C; and
- c) The word 'In', to indicate that it is calibrated to contain the liquid.

9.2 BIS Certification Marking

The product(s) confirming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

10 PACKING

10.1 The pipette may be packed as given in $\underline{10.2}$ or as agreed between the supplier and the purchaser.

10.2 The pipette shall be clipped on to a suitable cardboard piece, either by self-clipping action on the cardboard or by a separate clip or rubber band. One pipette so mounted shall be packed in a cardboard carton along with the connecting tube and the mouth piece, both attached, and placed in a paper envelope. In case the connecting tube is of rubber, it shall be given suitable sprinkle of French chalk.

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

Medical Laboratory Instruments Sectional Committee, MHD 10

Organization	Representative(s)	
All India Institute of Medical Sciences, New Delhi	DR SUDIP KUMAR DATTA (<i>Chairperson</i>) Dr Tushar Sehgal (<i>Alternate</i>)	
Association of Indian Medical Device Industry, New Delhi	SHRI RAKESH JAIN SHRI SHAILESH PATEL (<i>Alternate</i>)	
Becton Dickinson India Private Limited, Gurugram	SHRI GAURAV VERMA SHRI NEERAJ SHARMA (<i>Alternate</i>)	
Bharati Vidyapeeth Medical College, Gurugram	COL MAHADEVAN KUMAR	
Borosil Glass Works Limited, Mumbai	SHRI SHRIKANT GANGAN Shri Jeevan Dogra (<i>Alternate</i> I) Shri Satish Chitriv (<i>Alternate</i> II)	
Borosil Technologies Limited, Pune	SHRI SREEJITH KUMAR P. S. Shri Mahesh Surve (<i>Alternate</i>)	
Boston Scientific India Private Limited, Gurugram	SHRI PRASHANTH PRABHAKAR SHRI DEV CHOPRA (Alternate)	
Central Drugs Standard Control Organization, New Delhi	SHRI SELLA SENTHIL	
CSIR - Central Scientific Instruments Organisation, Chandigarh	SHRI NEELESH KUMAR Dr Sanjeev Soni (<i>Alternate</i>)	
CSIR - National Physical Laboratory, New Delhi	DR G. SUMANA DR RAJESH (Alternate)	
Directorate General of Health Services, New Delhi	Dr Naresh Panchal	
Dr Ram Manohar Lohia Hospital, New Delhi	PROF (DR) ARVIND AHUJA DR SASWATI DAS (Alternate)	
Hindustan Syringes and Medical Devices Limited, Faridabad	PRADEEP SAREEN SHRI P. K. SHARMA (<i>Alternate</i>)	
Holy Family Hospital, New Delhi	DR ADITI SHRI NEIL MILTON (Alternate)	
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Indian Council of Medical Research, New Delhi	DR B. C. DAS DR SANJAY GUPTA (Alternate)	

Organization

Kalam Institute of Health Technology, Vishakhapatnam

Magnus Opto Systems India Private Limited, New Delhi

Maulana Azad Medical College, New Delhi

Ministry of Consumer Affairs, New Delhi

- Ministry of Environment Forest and Climate Change, New Delhi
- National Accreditation Board for Testing and Calibration Laboratories, Gurugram

National Centre for Disease Control, New Delhi

National Institute of Pathology, New Delhi

- Post Graduate Institute of Medical Education and Research, Chandigarh
- Schott Glass India Private Limited, Pune
- Shriram Institute for Industrial Research, New Delhi
- Terumo Penpol Private Limited, Thiruvananthapuram
- Thermo Fisher Scientific India Private Limited, Mumbai
- University College of Medical Sciences and Guru Teg Bahadur Hospital, New Delhi
- Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi
- Voluntary Organisation in Interest of Consumer Education (VOICE), New Delhi

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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