

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

(Not to be reproduced without permission of BIS or used as an Indian Standard)

भारतीय मानक मसौदा

रक्त आधान के लिए फिल्टर और फिल्टर चैम्बर के लिए विशिष्टता

(IS 4445 का पहला पुनरीक्षण)

Draft Indian Standard

Specification for Filter and Filter Chamber for Blood Transfusion

(First Revision of IS 4445)

ICS 11.040.20

Hospital Equipment and Surgical Disposable
Products Sectional Committee, MHD 12

Last Date for Comments: 15 September 2023

FOREWORD

(Formal clause will be added later)

This standard was originally published in 1967. The first revision of this standard has been brought out to align the cross references to the latest standards.

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 same as that of the specified value in this standard.

1 SCOPE

This specification covers the requirements of filter and filter chamber used in the blood transfusion apparatus.

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.

<i>IS No.</i>	<i>Title</i>
IS 1382: 1981	Glossary of terms relating to glass and glassware (First Revision)
IS: 2303-1963	Method of grading glass for alkalinity.
IS 3692: 1975	Specification for rubber closures, pharmaceutical (First Revision)

3 MATERIAL

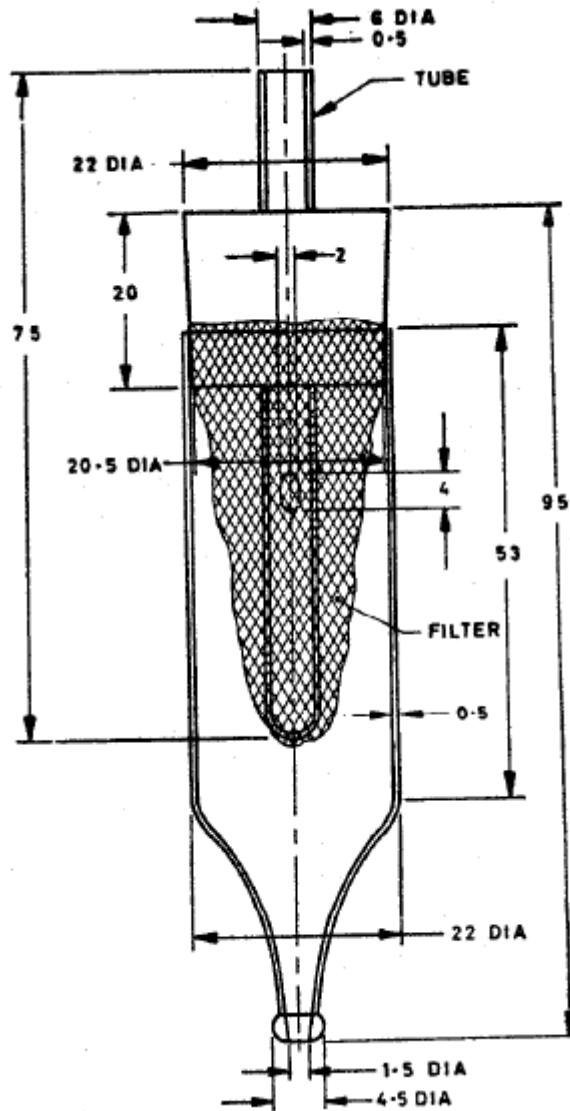
3.1 The filter tube and chamber shall be made from clear, colorless, neutral glass (for definition see IS: 1382). The glass shall pass the alkalinity test prescribed in IS: 2303 for Type I glass.

3.2 The filter shall be made from silk.

3.3 The bung shall be made from rubber; conforming to IS: 3692.

4 SHAPE AND DIMENSIONS

The shape and dimensions shall be as per Fig. 1.



All dimensions in millimeter (Nom).

FIG. 1 FILTER AND FILTER CHAMBER FOR BLOOD TRANSFUSION

5 WORKMANSHIP AND FINISH

5.1 The filter tube and chamber shall be well-annealed, free from bubbles and as far as possible, free from striae, stones and other visible defects (for definitions *see* IS: 1382). The ends shall be smoothly rounded in the flame. It shall be capable of being easily cleaned. It shall pass the thermal shock test, dry heat test and autoclave test specified in 5.1, 5.2 and 5.3 respectively.

5.2 The filter shall have a filtering area of not less than 32 cm². The filter material shall be minimum of 80 percent as efficient as a sieve having a mesh with an average pore size of 0.212 mm square and a thread of 0.1 mm diameter (the reference filter material). The filter shall be disposed of after using it for one transfusion.

6 TESTS

6.1 Thermal Shock Test – The filter tube and chamber shall be boiled in water for 30 minutes, then transferred to water at about 20°C. The glass shall not develop any chipping or cracking.

6.2 Dry Heat Test – The filter tube and chamber shall be subjected to a dry heat test in a sterilizing oven at $180^{\circ} \pm 2^{\circ}\text{C}$ for 30 minutes. The glass shall not show deterioration in any way nor develop any crack or chipping.

6.3 Autoclave Test – The filter tube and chamber shall be autoclaved at a steam pressure of 1.4 kg/cm^2 for a period of 30 minutes. The glass shall not show deterioration in any way nor develop any crack or chipping.

7 MARKING

7.1 The filter and chamber shall be marked with the name of the manufacturer, his initials or trade-mark.

7.2 BIS Certification Marking

The product(s) conforming 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 product(s) may be marked with the Standard Mark.

8 PACKING

The filter tube and chamber shall be packed as agreed to between the manufacturer and the purchaser. However, the recommended procedure is as follows:

‘Each set of filter tube and chamber shall be wrapped in suitable paper and packed in lots of 24 in suitable cartons ‘.