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भारतीय मानक मसौदा
चिकित्सीय जूते – विशिष्टि

Draft Indian Standard
Therapeutic Footwear – Specification

ICS 13.340.50

Assistive Products including Rehabilitation Appliances, Orthotic and Prosthetic Items Sectional Committee, MHD 09	Last date for Comments: **02 August 2025**

FOREWORD

(*Formal Clauses will be added later*)

Therapeutic footwear is used for relieving foot conditions, generally intended for individuals having diabetes which leads to neuropathic at-risk feet, where nerve damage (neuropathy) reduces sensation, especially in the feet. This makes it hard to feel injuries, pressure, or temperature changes, increasing the risk of unnoticed cuts or sores. The footwear physical safety requirements, test methodology, technical specifications, and instructions are also mentioned in the standard.

This draft standard includes the testing methodologies as per ISO 16187: 2013 Footwear and footwear components — Test method to assess antibacterial activity; and ISO 22649: 2016 Footwear – Test methods for insoles and insocks — Water absorption and desorption, which provides effective treatment to the end user.

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 standard specifies the general and safety requirements of therapeutic footwear designed for individuals having diabetes, neuropathic at-risk feet, and high risk of foot ulcers. It specifies the testing parameters for therapeutic footwear, in order to assess the suitability for the end use.

2 REFERENCES

The standard given below contains 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 edition of these standards:

IS No.	Title
IS 8751 (Part 1): 1978	Footwear sizes in mondopoint system: Part 1 Fundamental characteristics
IS 8085 (Part 1): 1986	Methods of test for footwear: Part 1 Dimensions, fitting, adhesion test, peel test, heat resistance test and ageing test (*first revision*)
IS 8085 (Part 12): 2023	Methods of Test for Footwear Part 12 Tensile Performance of Elastic Materials
IS 8085 (Part 25): 2024	Methods of Test for Footwear Part 25 Slip Resistance

3 TERMINOLOGY

For the purposes of this standard, the following terms and definition apply.

3.1 Rocker Angle

The angle between ground and curved section of footwear’s sole, typically located under the forefoot, which creates a rolling motion when walking.

3.2 Apex Angle

The angle formed between the flat part of the sole and the curved section of the sole at the point where the outsole begins.

3.3 Insole

A footwear insert that provides support, cushioning and pressure relief.

3.4 Outsole

The bottom, exterior part of the footwear that directly contacts the ground.

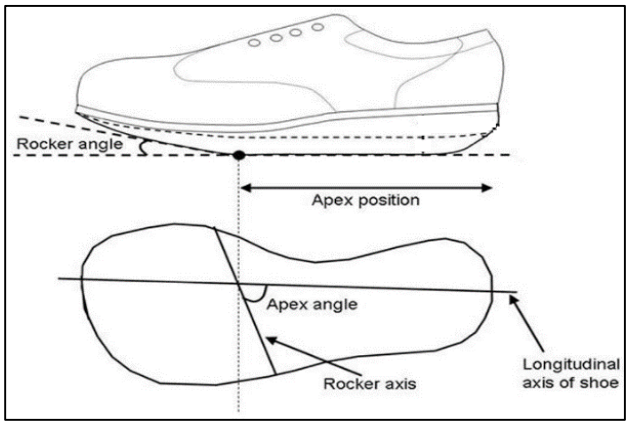

Fig. 1 FOOTWEAR, APEX POSITION, ROCKER ANGLE, AND APEX ANGLE, TYPICAL

4 GENERAL REQUIREMENTS

4.1 The footwear shall fit properly and fasten snugly to prevent movement of the foot. It shall provide support and accommodate the shape of the foot and any bony deformities. Orthotics or insoles shall be in accordance with IS 8751 (Part 1): 1978.

4.2 Extra depth/removable insoles may be present for the insertion of custom-made orthotics/insoles that provide good heel control to ensure sideways stability.

4.3 The footwear shall have the thickness of the insole in the range of 8-10mm.

4.4 The outer layer, outsole, and insoles of the footwear shall be made of materials that are durable and washable as per Annex A.

4.5 The footwear rocker angle shall be in the range of 15-20 degrees.

4.6 The footwear apex angle shall be 52% of the footwear length.

4.7 The footwear shall have width more than the widest part of the forefoot by 12.7 mm.

4.8 The length of footwear shall be greater than 12.5 to 15.8 mm compared to the longest toe.

4.9 The footwear shall be at least 4.76 to 15.8 mm deeper than the normal footwear measurement to provide extra depth for insoles and orthotic support.

5 TESTS

5.1 Abrasion Test

The Abrasive test shall be used to measure the volume loss of the therapeutic footwear to check durability.

The abrasion resistance index in footwear shall be calculated based on the DIN abrasion tester with test equipment conditions as follows:

a) Rotational speed: 40 RPM;
b) Diameter of cylinder: 150 ± 0.2 mm.

The therapeutic footwear's abrasion resistance index shall be in the range of 180 mg to 220 mg of mass loss.

5.2 Dimension, Fitting, Adhesion, Peel, Heat Resistance, and Ageing Test

The therapeutic footwear shall be tested for dimensions, fittings, adhesion test at toe and side, peel test, heat resistance test, and ageing test as per IS 8085 (Part 1): 1986.

5.3 Tensile Strength

The elastic materials used in therapeutic footwear shall be evaluated using the strength/ elongation graph, which is obtained from the tensile strength test as per IS 8085 (Part 12): 2023.

5.4 Rebound / Resilience

The rebound capacity of therapeutic footwear important for shock absorption to be evaluated as follows:

a) The test specimen shall have a diameter of 29 to 53 mm and a thickness of approximately 11 mm, it shall be placed in the clamping device;
b) The hammer shall be placed in a 90-degree vertical direction to the test specimen and finely touching it;
c) The pendulum shall be dropped onto the same part of the test specimen 3 times from a horizontal position, further pendulum shall be dropped another 3 times and the elasticity is measured from the scale. The average of the last 3 readings in the result shall be taken in consideration.

The rebound/ resilience test percentage shall have impact shock in the range of more than 60%.

5.5 Shore Hardness Measurement

The shore hardness of therapeutic footwear insole material shall be soft and shock-absorbable to prevent pressure ulcers on sensitive diabetic feet.

a) The test setup includes a shore durometer; the shore hardness measurement test evaluates the resistance of a footwear material against the penetration of a body;
b) The test shall have 3 main components – for hard materials the machine uses a needle, for foam materials such as midsoles, a machine with a ball tip is used and softer material shall be tested with a flat needle tip;
c) The test shall be done at 23 degrees with relative humidity of 50%.

The shore hardness of the material shall be in the range of 15 to 35 Shore A.

5.6 Compression Set

The compression of therapeutic footwear shall be tested to ensure the high durability of the midsole foam. The test determines the ability of a midsole foam to return to its original thickness after being compressed/deflected at certain temperature and duration.

The testing equipment shall have two metal plates, caliper, screws and a spacer whose size is based on the specimen thickness. The testing to be carried out as follows:

a) Initially the original thickness of the test specimen with a caliper [d (0)] is measured;

b) The specimen is placed between two metal plates and then screwed down to 50% thickness of the test specimen [d (1)];
c) The entire test apparatus remains 6 hours at 50°C in an air circulating oven;
d) After the required time the test specimen is removed and cooled down for 30 minutes at room temperature (23°C ± 2°C) on poor thermally conducting surface, such as wood;
e) After the resting time, the thickness of the test specimen is tested one last time [d (2)].

The compression set shall be calculated in terms of percentage as per the formula given below,

$$CS = \frac{d0 - d2}{d0 - d1} \times 100$$

d0 – Specimen thickness, original;
d1 – Spacer thickness, 50% of original specimen thickness;
d2 – Specimen thickness, post-compression.

The low CS percentage indicates a longer durability in both the function and design intent of the midsole foam.

5.7 Slip Safety

The therapeutic footwear shall be tested as per IS 8085 (Part 25): 2024 in one or more of the following modes,

a) Forward heel slip at angled contact;
b) Backward slip on the forepart;
c) Forward flat slip.

5.8 Water Absorption and Desorption

The therapeutic footwear shall be tested with an insole absorption and desorption tester to determine the water absorption and desorption of insoles, irrespective of the materials as follows:

a) The insole of therapeutic footwear shall be tested with an insole test specimen with a brass roller of diameter (120±1) mm and width (50±1) mm placed over the test piece;
b) The testing platform shall be covered with a roughened upper surface and with sufficient perforations to allow the surface to be kept wet by a flow of water through the platform. The upper surface of the platform shall be covered by strip of cotton gauze;
c) The clamps shall be used to hold the test piece with slight tension to maintain the sample;
d) The platform shall be equipped with supplied water, and to drain the excess water during testing;
e) The roller of the test specimen shall move to-and–fro motion along the X-X-axis, with an amplitude of (50±2) mm about a point directly over the mid-point of test piece and frequency of (20±1) cycles per minute;

f) The roller of the test specimen shall press the platform, test piece with a force of (80±5) N.

The water absorption (WA) shall be calculated in grams per square metre using formula (1),

$$WA = \frac{MF - Mo}{A} \quad (1)$$

Where,
Mo is the initial mass of the test piece, i.e. in its dry condition, in grams;
MF is the final mass of the test piece, i.e. in its wet condition, in grams;
A is the area of the test piece, in square metres.

The result shall be the average of the two results.
The water absorption shall be nearest to 1 g/m2.

The water desorption (WD) shall be as a percentage of mass using formula (2),

$$WD = \frac{MF - MR}{MF - Mo} \times 100 \quad (2)$$

Where,
Mo is the initial mass of the test piece, in grams;
MF is the final mass of the test piece, in grams;
MR is the mass of the reconditioned test piece, in grams.

The water desorption shall be nearest to 1 %.

5.9 Antibacterial Activity

The therapeutic footwear shall be tested quantitatively to evaluate the antibacterial activity of footwear and components:

a) The components or material in the footwear claimed as antibacterial, including upper, lining, insole, insock, and outsole shall be tested separately;
b) The test sample shall be at least 80% of the surface area of the component or material. If a single material accounts for less than 80%, two components or materials shall be used in the composition of the component;
c) The test specimen shall be about 500 mm^2, for the static challenge test method the area of the test specimen shall have a thickness of less than 2 mm;
d) If it is impossible to lower the thickness of the test specimen (for example, components are thicker and cannot be separated or cut without changing critical properties like surface morphology which may affect how the bacteria interact with the surface), the thickness shall be indicated in the test report;
e) At least six test specimens shall be taken for each material or component and each test strain;
f) Absorbent single material shall be tested for static challenge test; Non-absorbent single materials shall be tested for film contact method; and for combination of absorbent and non-absorbent materials dynamic challenge test shall be conducted.

NOTE – The stepwise details of the challenge test are given in Annex A, Annex B, and Annex C of ISO 16187: 2013 and the antibacterial activity ratio of footwear components shall be calculated as per clause 11 of ISO 16187: 2013.

6 TEST REPORTS

For each test method, the test report shall contain the following information:

a) Name and address of the testing laboratory;
b) Date of issue of the test report;
c) The reference of the sample;
d) The results as defined in each test method;
e) The measurement uncertainty (when requested by the customer);
f) Any deviation from the test method.

7 MARKING

7.1 The therapeutic footwear shall be marked legibly with the following:

a) Size;
b) Type;
c) Identification of the source of manufacturer or brand name;
d) CF 4 to be marked in case colour fastness to light test is claimed;
e) CR to be marked in case flexing resistance for cold region is claimed.

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 PACKAGING

The therapeutic footwear shall be packed as agreed to between the purchaser and the manufacturer. Each individual package shall contain footwear of one size only and may be marked with the name of the item, size, colour, and type, identification of the source of manufacture and batch number and any other marking if so desired.

Annex A

(Sub-clause 4.4)

Material Requirement

A1 Outer Layer Material

The common acceptable materials with reinforced areas over the toes and cupping the heel are as follows:

a) Leather;
b) Canvas;
c) Fabric;
d) Mesh.

A2 Outsole Material

Outsole materials shall have comparable properties or the same materials as mentioned below:

a) Leather;
b) Rubber;
c) Polyurethane.

A3 Insole Material

Insole materials shall have comparable properties or the same materials as mentioned below:

a) Ethylene vinyl acetate;
b) Polyurethane foam;
c) Micro-cellular rubber.

Annex B

Bibliographic References

B1 Reddie M, Shallal C, Frey D. A Scoping Review of Footwear Worn by People with Diabetes in Low- and Middle-Income Countries: Implications for Ulcer Prevention Programs. Glob Health Sci Pract. 2023 Apr 28.

B2 John, Anulekha Mary; Charley, Jessilin K.; Joy, Jibily. Assessment of Footwear among Patients with Diabetes Mellitus: A Cross-Sectional Descriptive Study from South India. Journal of Diabetology 12(1): p 41-45, Jan–Mar 2021.

B3 Ahmed S, Barwick A, Butterworth P, Nancarrow S. Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review. J Foot Ankle Res. 2020 Jun 4.