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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

सिंथेटिक पुरुष कंडोम के साथ स्नेग्धकारी की अनुकूलता

Draft Indian Standard

Compatibility of lubricants with synthetic male condoms

[ICS 11.200]

Obstetric and Gynaecological Instruments and Appliances Sectional Committee, MHD 03	Last date for comments:**27 September 2025**

NATIONAL FOREWORD

(*Adoption clause will be added later*)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 4074, Natural rubber latex male condoms — Requirements and test methods	IS/ISO 4074: 2015 Natural Rubber Latex Male Condoms— Requirements and Test Methods (*first revision*)	Identical
ISO 19671, Additional lubricants for male natural rubber latex condoms — Effect on condom	IS 17810 : 2022/ISO 19671 : 2018 Additional Lubricants for Male Natural Rubber Latex Condoms — Effect on Condom Strength	Identical

ISO 23409, Male condoms — Requirements and test methods for condoms made from synthetic materials	IS/ISO 23409 : 2011 Male Condoms — Requirements and Test Methods for Condoms Made from Synthetic Materials	Identical

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done 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.

Scope

This document provides guidance on assessing the effect or compatibility of an additional or personal lubricant with synthetic male condoms (excluding synthetic polyisoprene condoms). It also applies to topical medicines and any other substances that come into contact with such condoms. It describes the measurement of changes in physical properties of the condoms after exposure to the test substance (i.e. lubricant, topical medicine, etc.) and specifies the pass/fail criteria for such changes.

This document is intended to be used for evaluating the compatibility of chosen additional lubricants or topical medicines with chosen synthetic condoms. Each lubricant type is evaluated specifically against each condom material for which compatibility is claimed.

This document is not applicable to the assessment of the compatibility of lubricants applied to a condom at the time of manufacture. It is not directly applicable to female condoms, although similar principles can apply.

Introduction

Weakening of natural rubber latex is known to occur after contact with certain lubricants, particularly petroleum-based products with relatively low molecular weights.

Similarly, lubricants can affect condoms made from other materials.

This specification was developed to assist in developing methods for lubricant manufacturers to determine whether or not a particular personal lubricant or topical medicine has a significant effect on the tensile and airburst properties of condoms made from synthetic materials. It is also applicable to topical medicines and other chemicals that might come in contact with vulval, vaginal, oral or rectal tissues, and hence with condoms.

Strictly, the tests described in this document only show the compatibility of a specific lubricant with a specific condom relating to a suitable baseline product (lubricant/control). However, depending on the purpose of those tests, one can generalize the results to similar condoms or lubricants.

This test method does not determine the safety of either the test substance or the condom.

This test method is intended to determine if the tensile or airburst properties of the condom have been significantly affected by the test substance. It is generally assumed that materials that adversely affect the physical properties of the condoms to a material extent will cause additional failure in use, although that has not been determined clinically.

Some substances used as additional condom lubricants contain volatile fractions which may affect condom strength when they are first applied, but then evaporate rapidly. The condom’s strength may (or may not) change again as a result. Depending on the duration of this effect, it may affect the condom's performance in use. Typical candidate substances that can transiently weaken a condom (depending on the condom material) include Cyclomethicone D5, lighter volatile fractions and phenyl trimethicone. Conversely, heavier volatile silicone fractions can be protective until they evaporate.

Condoms made from polyisoprene behave similarly to natural latex condoms, and may be tested according to ISO 19671.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to ISO/TS 23148:2024 or kindly contact:

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