OPERATIONAL GUIDANCE

Standardization of Disposable & Reusable Sanitary Napkins in India

DEVELOPMENT SOLUTIONS INC
IDEAS to ACTION

Reproductive Health
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SECTION I

Why are standards for menstrual products needed?

Menstrual products are intended for the purpose of safe and hygienic management of menstruation by absorbing or collecting menstrual blood. They range from disposable sanitary napkins and tampons, reusable sanitary napkins, and menstrual cups. Creation and adoption of standards for disposable and reusable menstrual products is essential for providing choice to adolescent girls to manage menstruation hygienically in all contexts. Standards can further address unmet need for menstrual materials, and simultaneously ensure access to quality products. A common definition of quality creates a framework for market entry of new product categories and supports the inclusion of all categories into policy discussions that unlock government funding for enhancing awareness and access.

The recently published definition of Menstrual Health[1] lays emphasis on "preferences, hygiene, comfort, privacy, and safety" of menstruators in the context of products. A common definition of safety, hygiene and comfort is necessary to ensure menstrual health of all those who experience menstruation. Such a definition must also be available for a basket of products to allow for menstruators to choose products as per their personal and cultural preferences.

For low-and-middle income countries (LMICs) in Asia and Africa, around 27 standards for disposable sanitary napkins and 14 for reusable sanitary napkins exist, with new standards being developed across several nations.

[1] Hennegan, J., Winkler, I. T., Bobel, C., Keiser, D., Hampton, J., Larsson, G., Chandra-Mouli, V., Plesons, M., & Mahon, T. (2021). Menstrual health: A definition for policy, practice, and research. Sexual and Reproductive Health Matters, 29(1), 1911618. https://doi.org/10.1080/26410397.2021.1911618

SECTION II

BIS Standards for Menstrual Products

In India, performance, and hygiene benchmarks for disposable sanitary napkins (IS 5405) have existed since 1980 and were updated in 2019. In 2021, standards for reusable sanitary napkins and pantyliners (IS 17514) have also been published by the Bureau of Indian Standards (BIS). Indian standards for sanitary napkins include requirements for the materials to be used, bio-burden testing, biocompatibility and compostability. There is a strong case for certification of menstrual health products by BIS given their legacy of trust with the Indian consumers for decades and robust systems of inspection, testing, and surveillance to ensure conformity to standards by manufacturers. While standards across the world must be purchased, BIS has made Indian Standards available at no cost to Indian government officers on www.manakonline.in. For manufacturers all details and processes regarding testing and certification can also be found on the website.

While there are over 50 mid and large-scale manufacturers and numerous other small scale production units operational in the country, according to BIS, there are only 14 licenses presently in operation for use of the ISI Mark for Disposable Sanitary Napkins and none for reusables. According to a study done by Development Solutions and WaterAid India, only 6 of 16 manufacturers interviewed complied with any version of the IS 5405 (1980 or 2019). Evidence suggests that manufacturers with licenses also do not comply across all their product offerings.

It is critical to note that compliance to these standards is voluntary in India and awareness amongst users of the quality standards is also low. While users are mostly unaware of the standard, even procurement tenders have seen wide variance in the adoption of the standard. Hence, there is limited demand pressures for manufacturers to comply with the standards. The study also identified various barriers to compliance that manufacturers face including awareness of process of testing, certification and licensing. Small scale manufactures and social enterprises especially face challenges due to limited resources and access to information. Access and affordability of testing centers also poses a significant challenge for manufacturers with limited in-house testing capabilities and financial resources since many tests require batch testing and recurring testing costs are high. There is stated need, even from procurement stakeholders, for awareness on the testing requirements and related quality control processes.

This guidance document has been developed with the objective to provide process information to both manufacturers and procurement agencies for strengthening compliance to standards for the overall goal of access to good quality products for menstruators across socio-economic profiles.

SECTION III

Testing Requirements for Sanitary Napkins Standardization

TABLE 1: Tests Included in Indian Standards for Disposable Sanitary Napkins (IS 5405:2019) & Reusable Sanitary Napkins (IS 17514:2021)

TYPE OF TESTS	DISPOSABLE SANITARY NAPKINS (IS 5405:2019)	REUSABLE SANITARY NAPKINS (IS 17514: 2021)	TEST METHOD	INDICATIVE COSTS
MATERIAL & DESIGN	Material Sizes Manufacturing, workmanship and finish	Material Sizes Manufacturing, workmanship and finish Dimensional stability	As per ISO 5405:2019	INR 8000-10,000
PERFORMANCE-CHEMICAL	pH	pH		
PERFORMANCE-PHYSICAL	Ability to withstand pressure after absorption	Ability to withstand pressure after absorption		
HYGIENE	Bioburden Presence of S.aureus	Bioburden Presence of S.aureus		
Material Safety: Biocompatibility (new addition)	Cytotoxicity	Cytotoxicity	ISO 10993-5	INR 25,000
	Skin irritation	Skin irritation	ISO 10993-23 (Previous Standard ISO 10993-10)	INR 35,000
	Vaginal Irritation	*Vaginal Irritation*	ISO 10993-23 (Previous Standard ISO 10993-10)	INR 70,000
			ISO 10993-10	INR 1,50,000
	Skin sensitization	Skin sensitization		
Environmental Safety	Biodegradability & compostability *(*new addition *and Optional)*		ISO 17088	INR 4,00,000
Additional Tests		Washability (First 5 washes)	ISO 6330	INR 1100
		Washability (Each additional wash)		INR 220

Supplementary Resources for Sanitary Napkins Standardization

To aid compliance, BIS has recently proposed limiting the biocompatibility criteria as a suggested requirement that can be decided as per terms agreed between buyers and sellers and not a necessary requirement for certification.

As a supplementary resource, BIS has also published a Product Manual for disposable sanitary napkins (IS 5405) to support testing of products for standardization. The Product Manual includes:

- Sampling Guidelines: Raw Materials, Grouping Guidelines, Sample Size
- List of Test Equipment (Indicative)
- Scheme of Inspection and Testing
- Scope of the license

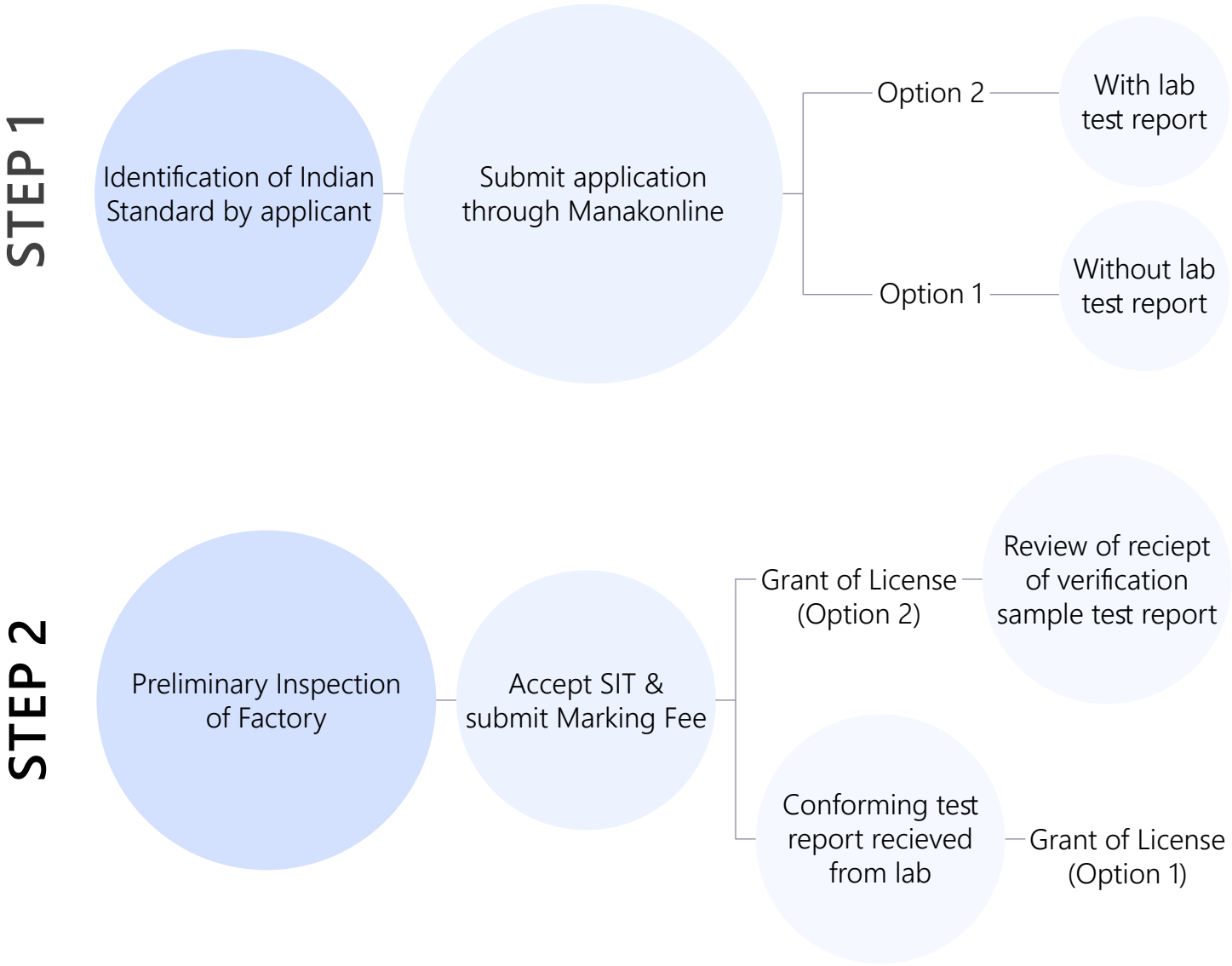
Important information on testing requirements for standardization can be accessed within the product manual as per the following guidance:

1. Scheme of Inspection and Testing
   - Tests to be done on products after licensing, and frequency of testing;
   - Requirement for establishment of internal testing facilities by licensed manufacturers
2. Grouping Guidelines
   - Requirements for testing product variations and varieties under a valid BIS license
3. Scope of License
   - Product variations eligible for the ISI mark if a license is received

SECTION IV

Process for obtaining BIS certification

The steps for the certification process are outlined below:



Presently, two versions of the disposable napkins' standard IS 5405:1980 and IS 5405:2019 are under concurrent running. BIS has advised new licensees and applicants to refer the revised standard. The 1980 standards will be phased out by early 2022 to allow manufacturers a transition period for adoption of the new standard.

Important Resource Links for Testing and Certification

1 Applicant User Manual
2 Product Certification Application Form Template can be accessed through
4 Testing facilities recognized by BIS:
- BIS testing facilities
- BIS recognized labs
- Empaneled labs

SECTION V

Strengthening Internal Quality Control

While mid and large-scale manufacturers have access to Good Manufacturing Process (GMP) certified facilities, this is often not the case for small scale manufacturers, especially those operating through community-based organizations. The guidelines below have been recommended to strengthen internal quality control processes of such units in the absence of GMP certified facilities. This will markedly enhance compliance to the standards, if certification is opted for.

1 Detailed guidance for ensuring hygiene has been included as Annexure in the IS 5405:2019 and IS 17514:2021 and should be referred for implementation in small scale units.

2 Raw material absorbency should be tested batch-wise to support the final product's fitness for purpose and maximize probability of complying with final product absorbency limits.

3 Storage of raw materials should be ensured in a cool and dry place – the raw material supplier should be consulted on ideal temperature and humidity conditions for ensuring that there is no microbial growth on raw materials. In highly humid contexts, air temperature and humidity control systems with proper ventilation should be installed to address this risk.

4 Maintenance of hygiene is also essential during transportation of raw materials and unpackaged product as well as during re-packaging done in small decentralized units.

5 Any products using oxo-degradable raw materials must disclose this fact on the packaging to ensure that the used product is safely disposed and is not composted or buried in the ground, for risk of eco-system exposure to microplastics.

6 Similarly, any products that claim compostability should provide guidance on feasible context-specific composting processes that can be used in the absence of large-scale composting infrastructure.

7 Additionally, a quality checklist should be developed and used as per a pre-decided schedule to ensure compliance to key quality control systems designed by the manufacturer. A simple example of such a checklist is specified on the next page.

Draft Internal Quality Control Report Format:

Note: This format is indicative only and may not be treated as exhaustive. This should be appropriately adapted to the organization's requirements.

DATE OF INSPECTION: DAY/MONTH/YEAR	
PRODUCT VARIANT:	
INSPECTOR:	
TYPE OF INSPECTION: (INTERMEDIATE/FINAL)	
LOT SIZE (NO. OF UNITS):	
SAMPLE SIZE (NO. OF UNITS):	
AQL* DEFECTS:	
TOTAL DEFECTIVE ARTICLES:	
STRUCTURAL CRITICAL DEFECTS: (YES/NO)	
RESULT: (ACCEPTED/REJECTED/ON HOLD)	

QUALITY PARAMETER	**DETAILS**
Materials	
Sizes	
Workmanship	
Finishing	
Packaging	
Marking	

QUALITY PARAMETER	Test Value	Within standard range (Yes/No)
Sizes		
Dimensional Stability (for reusables)		
pH		
Ability to withstand pressure after absorption		
Bioburden		
Presence of S. aureus		
Washability (for reusables)		

DEFECTS	**REMARKS**
Checked by (Signature) Date	

**Acceptable Quality Level as per IS 2500 (Sampling Inspection procedures) should be used.*

THE TEAM

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