GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
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Specifications and Quality Control (QC) parameters for testing non-medical fabric masks for community use

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The non-medical fabric mask is not intended for use by health workers.

This guideline is non-binding and not a regulatory requirement from DGDA.

Concerned manufacturers may use these guidelines to seek confirmation that their product(s) complies with the requirements in the guideline.

Acknowledgements

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Foreword:

In recent times the world has been concerned with the infection of a novel virus, which has originated from the SARS (Severe Acute Respiratory Syndrome) virus family, known as the Corona virus (SARS-CoV2, also known as Covid-19). The disease caused by COVID-19 has been declared as a global pandemic by the World Health Organization (WHO). Initiating in Wuhan, China in around December 2019-January 2020, this virus has spread all over the world, causing deaths of thousands and infecting millions every day. Till date there has been over fourteen million confirmed cases and over six hundred thousand confirmed deaths caused by COVID-19 throughout the world (WHO, 17 July 2020).

Knowledge about transmission of the COVID-19 virus is accumulating every day. According to the current evidence, COVID-19 virus is primarily transmitted between people via respiratory droplets and contact routes. A respiratory droplet is a small aqueous droplet produced by exhalation, consisting of saliva or mucus and other matter derived from respiratory tract surfaces. Respiratory droplet sizes range from 5 to 100 micron (μm). Droplet transmission may occur when a person is in close contact with an infected person (with or without strong symptoms) and exposure to potentially infective respiratory droplets occurs

Taking into account the available studies, general public is advised to wear non-medical barrier mask as a part of a comprehensive approach to suppress community SARS-CoV-2 transmission. A reusable fabric mask or cloth mask can be used as a barrier mask to minimize the projection of user's respiratory droplets saliva, sputum or respiratory secretions when talking, coughing or sneezing. This fabric mask may also limit penetration in the user's area of nose and mouth of the respiratory droplets from external origin without claiming the user protection. It also prevents user's area of nose and mouth from any contact with the hands.

Aiming to limit spreading of respiratory droplets (5 to 1000 μm), standards and guidelines are set for non-medical fabric masks for community use. To do so, a series of stakeholder consultations were conducted with the representatives of mask manufacturers, fabric producers, testing laboratories, academia, and biosafety experts. The following key parameters were considered to design fabric mask for community use: i) particulate filtration efficiency (w.r.t. respiratory droplets), ii) breathability of the fabric mask, and iii) chemical properties of the material.

Considering the breathing resistance and filtration efficiency, parameters were set for three types of fabric masks:

i) Standard fabric mask (Level 70%): will offer high breathability (Breathing resistance ≤40 Pa/cm^2) and comfort to the user with a standard filtration efficiency (70 per cent or more) for 3-micron (μm) particles.

ii) Standard fabric mask (Level 90%): will offer high filtration efficiency (90 per cent or more) for 3-micron (μm) particles with comfortable breathability (Breathing resistance ≤50 Pa/cm^2) to the user

ii) High performance fabric mask: this high-performance mask will offer very high filtration efficiency (95 per cent or more for 3-micron (μm) particles, and 70 per cent or more for 0.3-micron (μm) particles), with standard breathability (Breathing resistance ≤60 Pa/cm^2) to the user.

Cloth Mask/ Fabric Mask

Cloth Mask or Fabric Mask is also known as Barrier Mask, Fashion Mask, Reusable Community Mask, Textile Face Coverings in different regions.

Supporting Standards/Guidelines:

- ✓ EN 14683 Type I and IR performance
- ✓ ASTM F 2100 level 1 or level 2 or equivalent
- ✓ AFNOR SPEC S76-001
- ✓ DNP TS C0042020007: 2020
- ✓ BS EN ISO 811:2018
- ✓ CWA 17553
- ✓ AATCC MXXX-2020: Face Covering Monograph
- ✓ WHO Advice on the use of masks in the context of COVID-19, Interim Guidance, 5 June 2020

Possible Test Parameters:

- ✓ Breathing Resistance (EN 14683)
- ✓ Differential Pressure (EN 14683:2019)
- ✓ Particulate Filtration Efficiency (F2299)
- ❖ Chemical Parameters: pH, Formaldehyde
- ❖ Wash able (ISO 6330, AATCC T150-2018)

Cloth mask/ fabric mask testing parameters and specifications[1]

Sl. No	Test Parameter	Unit	Minimum/Maximum Requirements	Remarks/References
1.	Breathing Resistance, Differential Pressure (EN 14683:2019, ASTM F2100, EN 13274-3, AATCC Face-Covering-Monograph, or equivalent)	Pa/cm^2	≤40 (**Standard Fabric Mask (Level 70%)**	EN 14683:2019, CWA 17553, AATCC MXXX-2020
			≤50 (**Standard Fabric Mask (Level 90%)**	
			≤60 (**High Performance Fabric Mask)**	
2.	Particulate Filtration Efficiency (CWA 17553, ASTM F2299, or equivalent)	%	≥70 (@3 µ) (**Standard Fabric Mask (Level 70%)**	CWA 17553, AATCC, Face-Covering-Monograph
			≥90 (@3 µ) (**Standard Fabric Mask (Level 90%)**	
			≥95 (@3 µ), ≥70 (@0.3 µ) (**High Performance Fabric Mask)**	
3.	pH	--	5.5-7.5	Ref: EU Standard; ISO 3071; AATCC 112; OEKO-Tex 100
4.	Formaldehyde	ppm	<16 (kids); <75 (adults)	ISO 14184-1; REACH Regulation (EU 2018/1513); OKEO-Tex Standard

* Acceptance Quality Limit: AQL 4%

Other requirements:

1. Cloth masks should serve as mechanical barriers for control of droplets. The mask should not be impregnated with any harmful chemicals. Fabric mask manufacturers should not have any false claims like Antimicrobial/antiviral/antibacterial properties. In case of claiming Antimicrobial/antiviral/antibacterial properties, the concerned manufacturer must submit evidence in support of this claim to prove safety and efficacy through biocompatibility and performance evaluation studies. This is to prevent the possibility of harmful chemicals being used in the masks and to prevent any false claims.
2. Fabric quality: Knit/Woven fabric used to manufacture cloth/fabric mask should comply with OKEO-Tex Standard 100 or equivalent. The inside part of the mask should have water-absorbing (hydrophilic) characteristics, and outside part of the mask should have hydrophobic (not easily absorb liquid) characteristics. Fabrics and materials used to develop mask should be biocompatible and shall not be known to cause irritation, allergenic effects or other toxic effect.
3. Packaging and Marking: Packaging (individual/bulk) should contain information about test standards, mask size, and instruction for use.
4. A minimum of five washes is required to claim reusability. The mask must keep its structural integrity and properties after the claimed number of washes. Number of Wash is measured according to the following standards ISO 6330, AATCC 150-2018, AATCC Face-Covering- Monograph, or equivalent (@60°C, 30min wash cycle with detergent).

[1] *Based on the level of Breathing Resistance, Differential Pressure, Particulate Filtration Efficiency cloth masks/fabric masks performance levels are mentioned detail in* ***Apendix-2, 3 & 3.***

APPENDIX-1

Materials (Ref: CWA 17553, AATCC MXXX-2020)

The materials used for manufacturing the face coverings shall be able to withstand handling and wear throughout the lifetime of community face coverings, indicated by the producer.

The producer shall take into account the following when selecting material:

- Its breathability.
- The ability to absorb moisture to prevent condensation falling on to the user.
- Multiple layers of fabrics may be used to achieve desired performance. Single-layer face coverings may not provide adequate filtration unless they are proved by testing. More than three layers may restrict breathing and may be heavy and bulky for thewearer.
- Fabric compatibility is important for multi-layer constructions. Fabrics with significantly different dimensional stability to laundering may cause fit or function issues if used together.
- Denser constructions and heavier fabric weights typically provide better particle filtration due to smaller spaces between the yarns or fibers. However, A balance of particle filtration and breathing resistance is required for a functional cloth mask.
- Fabrics and fittings should not contain hazardous chemicals. Fabrics, fittings and reagents used to manufacture cloth mask should be biocompatible (specially the parts come into direct contact with the skin of the user). These materials shall not be known to cause irritation, allergenic effects or other toxic effect.
- For reusable cloth mask, the materials used shall withstand the cleaning cycles, detergents and methods specified by the producer.
- Fabrics with high stretch, including jersey knits, may pose a challenge because stretching increases the spaces between yarns. If used, such fabrics should be combined with a more stable layer in the construction of cloth mask.
- Moisture management of the inner and/or middle layer of the mask is important. Fabrics that move or hold moisture away from the face may be more comfortable for the wearer. Humid environments also promote formation of larger droplets which are easier to retain with a cloth mask.
- Coated or laminated fabrics may have undesirable properties including high breathing resistance and chemicals unsuitable for direct contact with mouth and nose.
- Avoid fabrics and findings containing hazardous chemicals.
- When selecting materials, the producer shall take into account the ability to be recycled or composted to ensure sustainability.

Face Mask Construction (Ref: CWA 17553, AATCC MXXX-2020)

Manufacturers shall consider the following key points to construct cloth mask:

- Facepiece should provide adequate covering the for mouth, nose and chin fitted with the head harness which can be head or ears attachment.
- Toavoid unnecessary seams as they may introduce potential areas for leakage. Seams and stitching create holes that may allow passage of more droplets than unstitched areas of fabric.
- Toavoid seams at nose and mouth area. Bulky seam allowances can cause pressure and discomfort to the wearer.
- To use appropriate seam construction to prevent seam allowances from interfering with fit or breathability, particularly for multi-layer assemblies.
- Touse appropriate needle and thread to make the smallest possible holes in sewing.
- Touse appropriate stitch length to ensure secure construction without unnecessary holes.
- Touse pleats, darts, or other construction techniques to shape cloth masks for a proper fit.

Packaging (Ref: CWA 17553, AATCC MXXX-2020)

Cloth masks shall be packaged in such a way as to protect them against any mechanical damage and anycontamination before use. Individual or grouped packages are at the producer's discretion. Package labels should generally be “conspicuous and accessible”. Label information should also be conspicuous and accessible in online, print media or other sales channels

Marking (Ref: CWA 17553, AATCC MXXX-2020)

The cloth mask to be placed on the market shall be clearly and durably marked with the information below on the smallest marketable package available or shall be legible through the packaging if the packaging is transparent and contain the minimum information below. The text shall be printed both in English and Bangla.

- The producer name, trademark, or other means of identification.
- The postal or web address at which the producer can be contacted.
- A means of product identification e.g. batch number.
- The filtration efficiency level/type of the product
- Breathability of the product
- Status of chemical toxicity of the fabric, stitching, fittings and reagents used to produce the product
- The type of community cloth masks: i.e. "reusable" or "disposable".
- The type of users i.e. "child" or "adult".
- The storage conditions.
- Wearing instructions: instructions on how a user puts on, wears, and removes cloth mask.
- Cleaning and drying instruction: instructions for home laundering
- The maximum number of washing cycles
- Disposable instructions: instructions for proper disposal of cloth mask. One example of disposal instructions is: “wash it with detergent before disposal.”

Warnings (Ref: CWA 17553, AATCC MXXX-2020)

- The cloth mask to be placed on the market shall include the warnings below, with the words "WARNING" in front of them. The text shall be printed both in English and Bangla.
- If you are ill, this cloth mask is unsuitable. Seek advice from your doctor.
- This product is not a medical device.
- Always check that the cloth mask is correctly fitted and covers your nose, mouth and chin. It is recommended that this cloth mask be worn on bare skin; beards can reduce the filtration efficiency to below the limits set out.
- If applicable: Cloth masks are not suitable for children under 3 years of age. Children between 3 and 12 years should be supervised while wearing the cloth mask. A cloth mask which hinders the user's ability to breathe when first put on is deemed unsuitable.
- This cloth mask does not replace protective measures (regular hand-washing, physical separation, reduced contact with other people). It minimizes the projection of user's respiratory droplets saliva into the environment.
- Do not use when participating in vigorous physical activity.
- Stop using this product at the first signs of damage.
- The cloth masks specified as reusable should be washed before the first use unless recommended by producer.

- Do not use dry cleaning and fabric softener.
- Clean the reusable cloth mask after each use.

Facial Dimensions to be considered to manufacture Cloth Mask

(Ref: CWA 17553, AFNOR SPEC S76-001)

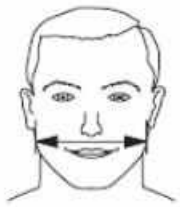
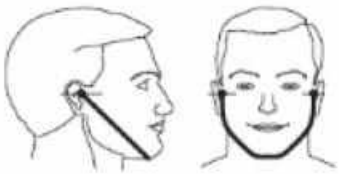
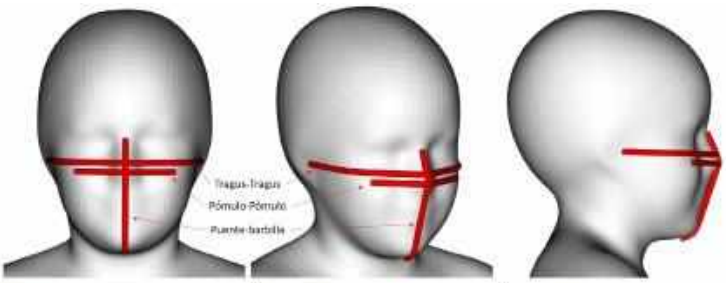
			
Bigonial breadth 132,5 – 144,5 mm	Chin-Sellium length 123 – 135 mm	Interpupillary distance 65 – 71 mm	Bitragion chin arc 295 – 315 mm

Figure 3 — Adult facial and head dimensions [8]



Age Range	Cheekbone – Cheekbone	Sellium – Chin	Tragion – Tragion	Head Circumference
3 – 5 yrs.	88 – 109 mm	93 – 127 mm	202 – 253 mm	477 – 549 mm
6 – 9 yrs.	94 – 116 mm	105 – 136 mm	220 – 279 mm	500 – 560 mm
10 – 12 yrs.	98 – 121 mm	114 – 146 mm	233 – 290 mm	515 – 580 mm

Figure 4 — Child face and head dimensions [3]