

# Bioburden in Sparsa's factories:

## What is it and how to reduce it?



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## I/ Introduction

Microorganisms are everywhere, in the air, in the soil, on and in us. It can be virus, bacteria or fungi. Some can be dangerous for human health; some are part of us and help us digest for example. They are also present in humans' genitals, and so in the vagina.

As they are everywhere, they will be present on the menstrual pads we are producing because menstrual products are not 100% sterile. What is important is their quantities and species. Indeed, some found on pads, would already be present in the vagina for example, and this won't be a problem. The problem is if bacteria which are considered as "dangerous" are found on pads (for example E.coli), or if the amount is too big, and can lead to disrupt the natural biotope living on the vulva and in the vagina. Then, infection or other diseases or health problem can appear.

For example, some bacteria, often found in vagina, can lead to diseases if their population are growing too much. If not, then there is no problem.

The definition of Bioburden is the number of microbial cells living on a surface or object that has not been sterilized.

This document is here to help us understand what means bioburden, and how to reduce it, to ensure that our pads are safe to use. It is not intended to go too deep on the biology of microorganisms, but rather to give an overview, and especially to give clear recommendations to reduce the bioburden. After a short explanation of the main conditions that bacteria and fungi need to grow, the source of bioburden in factories will be identified. Then, the standard of Nepali sanitary pad on bioburden will be explained, and finally recommendation to decrease bioburden in our factory will be detailed.

## II/ Conditions for Bacteria and Fungi development

Microorganisms quickly reproduce themselves if the environment conditions are favourable to them. Each species of bacteria, and fungi will have different preferences, but in general they will thrive in a humid and warm environment, with adequate nutrients (organic matter). For example, a fungus that everyone knows is mould. It grows in houses and apartment, with a high humidity, and is potentially dangerous for health.

Given that different species thrive in different environments, literature gave a wide range of humidity and temperature to avoid growth of microorganisms. Also, several Humidity measurements are given to control microorganisms growth, such as Relative humidity, absolute humidity, material moisture, etc. Here we will focus on Relative Humidity (RH), and material moisture.

RH is the degree of saturation of the air with water. So if RH is 100%, the air is totally saturated with water. Now RH is always given with the temperature, as when the temperature changes, RH changes. Indeed, higher the temperature, more water the air can contain. So let's say we have 100% RH with 20°C, if the temperature increases, RH will drop. In case this is not clear, you can watch this very short video (<https://www.youtube.com/watch?v=PNsF5PzNVJo>).

The material moisture is simply the amount of water present inside the materials.

As water is crucial for bacteria or fungi development, we must ensure that there is not enough water in the material or environment for microorganism to grow.

In Nepal throughout the year, the weather is changing, and the humidity will be higher during the rainy season, or during the mornings in winter, and less in the hot season. This is important as the weather will have an impact on bacteria and fungi growth.

## III/ Source of bioburden

During the whole process of both factories, there are a lot of areas where there is a risk of contamination. We can divide the source of bioburden in 4 main sources, detailed below.

### a) Personnel

One of the main contributors to microorganism is actually us, Humans! We are indeed, losing in average 1 million cells per day (skin, hairs, saliva, etc). Those microorganisms can easily finish on the pad. This is why it is highly important that everyone manipulating our pad or our raw materials, are educated on how to reduce bioburden, and apply strictly all the rules.

### b) Raw materials:

Another source is the raw material. As we are buying some of them, we cannot be sure that they are “clean”, however we can make sure that the dirty packaging is get rid of in a proper way, or the storage is avoiding any contamination. In addition, we should try to ask our suppliers to have a certificate analysis from their materials including a bioburden count.

Regarding our banana fibres, here we are in control, and we need to be cautious. For example, we need to ensure that the paper is dry to avoid mould. Paper is indeed a hygroscopic material (material absorbing the water present in the air around), Which means that if the humidity is too high, the paper moisture will be high, which might help mould to grow (See annex 2 for more detail). In addition, paper is mostly food for bacteria and fungi.

The main risk for paper storage is fungi, as paper bio receptivity for fungi (ability of a material to be colonized by living organisms) is quite high, due to his hygroscopic nature, and composition. This is why mould growth in paper conservation is a big topic, and museum for example must be extra careful.

### c) Manufacturing process:

Here we find any source coming from the process, for example the water used to produce our banana paper. If the water is contaminated by bacteria, those bacteria will be on our paper.

We also need to be careful on the air used for our banana fibre mattress machine, as compressed air can be a source of bacteria. Our machine should also be clean, etc.

#### d) Manufacturing environment:

As explained above, microorganisms are present in the air. So, if nothing is done to try to reduce the microorganism load in the air of the production area, it might contaminate our pad. For that, several systems exist to lower the risk. For example, having an air filtration system, having rules to follow while entering the room, controlling temperature and humidity, cleaning schedule, etc.

## IV/ Standard for menstrual pad

Reducing bioburden in our factories, and in fine in our sanitary pad, is also mandatory if we want to receive the certification from the Nepali government. Indeed, in the Nepali standard for sanitary pad, it is written that the sanitary pad should not have a total viable count of bacteria and fungi of more than 1000 cfu/g (colony forming unit per gram) and staphylococcus aureus (a bacteria specie) shall be absent.

To obtain a result in cfu/g, the analysis consists of taking a piece of the pad, extracting the bacteria and fungi from it, then cultivated them, and finally counting the number of colonies formed.

A study done in India, tested several brands of menstrual pad available on the market, and the results are quite diverse, the bacterial bio-burden of all the sanitary napkins was found between 120 and 4800 cfu/ml while fungal bio-burden ranged from 110 to 4900 cfu/ml. So, some were actually way over the limit of 1000 cfu/g. This means that we must be careful, as it seems to be easy to go over the limit.

In addition, the standard requires several good manufacturing practises that must be put in place, if we want to get certified at one point. The list is accessible Annexe 1.

## V/ Reducing Bioburden in our factories.

To reduce the bioburden, 2 series of measures have been developed. The first one should be done to ensure a cleanliness that might be enough. If it is not the case, then actions from the second series should be put in place to reduce even more the bioburden. The first series is called basics, and the second advanced.

### a) Fibre factory basics:

- Having regular check of the bacteria and fungi amount in the water after the filter. (once every quarter)
- Once the fibres are boiled, they should be considered as cleaned. This means:
  - o Only having cleaned hands wearing gloves while manipulating them => communication with the operators. Before manipulating the fibres, the operators must either cleaned their hands with soap or sanitize them with an alcohol solution and then wear clean gloves.
  - o Cleaning the equipment's used to manipulate them with soap or Alcohol solutions on a regular basis (beater, rincer, VAT, buckets, etc). We can start with once per week and see.
- Drying the paper in the solar dryer. Once the paper is dry (material moisture less than 12 %), put them in plastic bags or plastic bins. The plastic bags or bins should be sanitized beforehand with alcohol solutions. It should be put in bags or bins inside the dryer if possible. To test the moisture, we can buy some sensors. The operators must manipulate the paper only with clean hands wearing clean gloves.
- The equipment (tray, thread, etc) where the paper is during the drying phase should also be cleaned once a week, with alcohol solutions.
- The solar dryer should be well ventilated. The opening for the ventilation should have filtered protecting the inside from dust, bugs and animals.
- Always storing the paper in their bags or bins, and quickly send them to the pad factory, where it is "cleaner".
- When stored, the plastic where the paper is should be close, not touching the ground, and not touching the wall.
- The fibres when stored, should not touched the ground, neither the wall. They can be put in bags to protect them from Dust.
- The cloth used to make paper should be cleaned as well, and stored properly (once dry put them in a plastic bin or plastic bag)

### b) Fibre Factory advanced:

- Covering the inside of the Hollander beater with Stainless Steel. This will facilitate the cleaning process and ensure that no paints residues finish in the paper.
- Cleaning the equipment in contact with the cleaned fibres every second day, with an alcohol solution
- When manipulating cleaned fibres, the operators must wear masks, gloves, clean clothes (waterproof apron sanitized with Alcohol solution)
- Microorganism checking in water every month
- Second plate of stainless steel bought for the screw press => the paper should only touch stainless steel, and not the press, or wood.

### c) Pad factory storage basics:

- Installing rack (shelves) to put the raw materials. The rack should not touch the walls, to ensure good air circulation. The materials should not touch the ground neither.
- Having a side of the room for finish product, and one side for raw materials.

- When reception of raw materials, we need to ensure that the packaging is still well around the material. To ensure to not bring too much dirt inside the factory, we could clean the packaging before putting the raw material inside the factory.
- Installing a relative humidity sensor in the storage room, and watch the humidity level, especially in winter, and rainy season
- Put rat and mouse traps, and regularly check them.
- Materials should be out of direct sunlight
- Mosquito net on the windows if needed
- Bringing the paper as often as possible in the pad factory, as the storage is safer in the pad factory than in the fibre factory

#### d) Pad factory storage advanced:

- Have a close room for storage (installing aluminium partition), where relative humidity, as well as temperature is controlled. And kept maximum with 60% RH and 30 °C
- Installing a fan to ensure good air circulation and a homogeneous air condition.

#### e) Cleaning and production area basics

- Trainings on hygiene for every employee of Sparsa and NIDISI who will often be in the pad factory, and in contact with the machines/raw materials, etc)
- Displaying on the wall posters showing hygiene rules
- Operators are following the protocol to get ready:
  - o Wash hands with soap
  - o Change clothes => use normal personal cloth which are not wear outside.
  - o Sanitize hands
  - o Put mask
  - o Put clean Apron
  - o Change shoes. No outside shoes allowed in the production area. The slipper used in production area must be used only for production area. If socks are not wore, feet must be cleaned.
  - o Put gloves
  - o Enter the room
  - o If the operator go on a break outside the room, gloves and mask must be change. Apron should be removed and not wear outside. After the end of the break, do the same procedure as above.
  - o If coughing or sneezing => mask must be change
  - o When gloves are worn, do not touch your skin with it. If sweat on the forehead for example, use your arm, not your hands.
  - o If sick, do not enter the production room. Stay at home.
- Each people entering the production area is following the operator's protocol.
- Production room:
  - o The AC filter must be often check/clean/changed.

- Important to be careful with the air from the air compressor => is there a filter, can we access it? Apparently, it might be source of bacteria.
- Door of production area must be always closed and if possible airtight.
- The pressure in the production area should be higher than in the corridor. Thus, the air when the door open, will always go from inside towards outside, to not bring any bacteria in. Normally this is happening with the AC, so no need to do anything.
- No food or drinks allowed in production area
- No check of phone in production room (phones are full of bacteria)
- Cleaning schedule:
  - Every equipment must be cleaned twice a week with alcohol-based sanitizer. (machines, working table, packaging machine, doorknobs, etc)
  - The floor must be cleaned (mopped with sanitizer) once a week. The floor must not be swept, as this will throw in the air a lot of microorganisms.
  - The walls and ceiling must be cleaned and sanitized once a month. (here we can see how often we need to do that).
  - After maintenance on the machine, it needs to be cleaned.
  - Empty the bins regularly
- Production:
  - Reduce as much as possible the opening of the door of the production area, to limit the number of microorganisms coming from outside.
  - Unpack the raw material in the storage room and then bring it in the production area. Remove the first layer of raw material before using it.
  - The pads must leave the room only when they are fully packaged.
  - Each pad is single packed, then 8 pads are inside the packaging. Then the 8 pads packaging are covered with plastic and then put in a big cardboard. Then stored.

## f) Laboratory test

To ensure that our pads are safe to use, on top of all the rules detailed above, they will be tested by an independent laboratory. The question here is how often they need to be tested. Especially at the beginning where the production will be very low. The Nepali standard requires to test the pad for hygiene (bioburden, pH, etc), only once per quarter, which is quite not often. At the beginning, we would need to do series of tests, to evaluate our pads. Once the production is running continuously, hygiene tests happening once a month seems fair.



## Conclusion

After this research and talk with experts, it seems that it is quite achievable to control the bioburden on our pad. Relatively simple actions can drastically reduce microorganism on our menstrual pad. Moreover, only few of them require investment, for most of them, it consists of behaviour change. However, the difficulty with behaviour change is to implement it, and ensure that it is followed. A crucial point to succeed in this, will be the organization of trainings on bioburden and hygiene rules, for every employee of Sparsa, and NIDISIs who are involved here (for example the technical team).

In addition, the very first results of bioburden testing on our pads, will arrive soon (after Dashain). Based on those results, we will be able to choose and implement a series of best practices listed in this report. We will be testing our raw materials at the same time than our pads, which will give us even more information, on the source of the bioburden, in case the results are over the limit. Thanks to this, we will be able to directly orientate our action on the most critical source of bioburden.

This report should be used as a basis for discussion on which actions to implement regarding bioburden, to ensure good hygiene, and the safety of the Sparsa pad.

## Annex

### Annex 1: Good manufacturing for Hygiene requirement from the Nepali standard for sanitary pad

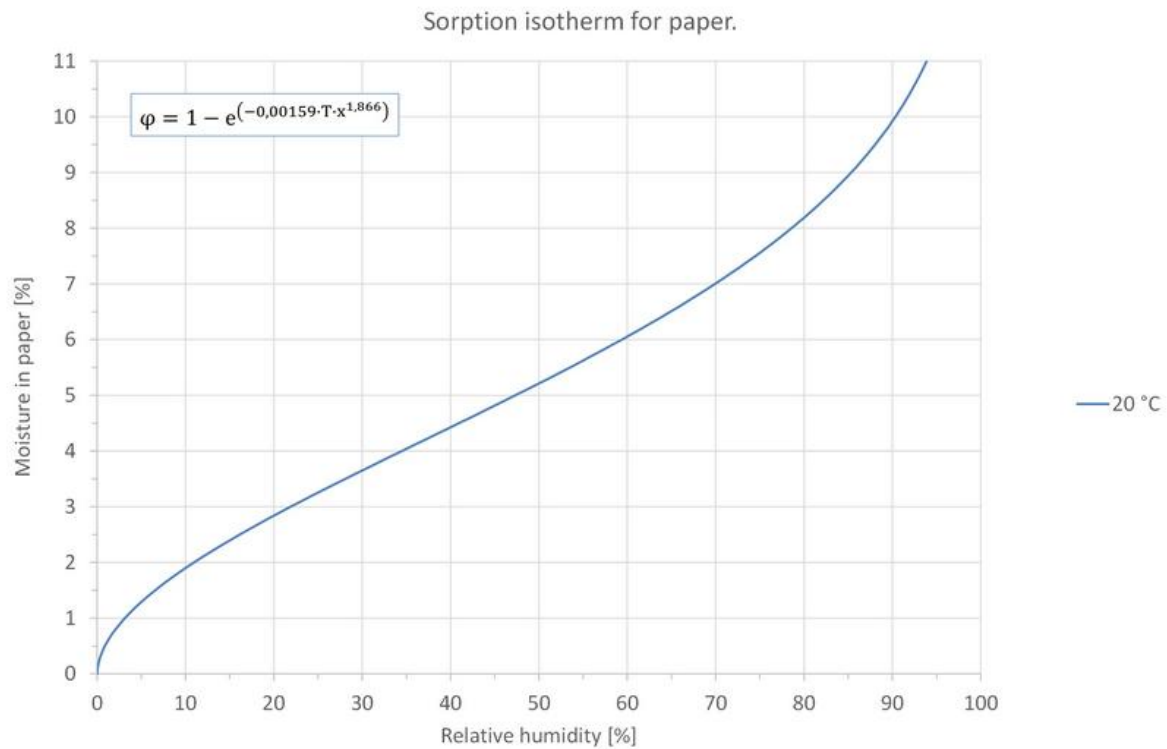
#### ANNEX C (Clause 7.3.3)

##### Good Manufacturing Practice for Hygiene Requirement

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumer use. Following are recommended guidelines for ensuring hygiene at facilities:

- a) Location should be free from objectionable odours, smoke dust and other contaminants.
- b) Separate areas shall be demarcated for storing raw materials, production and final product storage.
- c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
- d) Toilet and hand washing station shall be provisioned away from storage/production area.
- e) Provision of 70 percent isopropyl alcohol (IPA) solution for hand sanitization inside the production facility.
- f) Appropriate lighting and proper ventilation of the facility shall be ensured.
- g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors, and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.
- h) Regular pest control measures shall be put in place.
- i) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.
- j) Poster sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc., shall be displayed.
- k) Pre-packed finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.
- l) Hand hygiene shall be practiced during manufacturing.
- m) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning disinfection of the equipment.

## Annex 2: Absorption of moisture paper



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[Cleaning Sanitizing Sterilizing Or Wishing It Away What Are We Doing To Control Bioburden \(pharmaceuticalonline.com\)](#)