wjpmr, 2017,3(8), 85-94

SJIF Impact Factor: 4.103

WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.wjpmr.com

Review Article

ISSN 2455-3301

WJPMR

METHODS FOR EVALUATION OF MICROBIOLOGICAL SAFETY, GUIDELINES GOVERNING THE QUALITY AND SURVEY ON MICROBIAL CONTAMINATION OF COMMERCIAL COSMETIC PRODUCTS - A REVIEW

Sanchita Choubey* and Suchitra Godbole

Department of Microbiology Dr. D. Y. Patil Arts, Commerce and Science College, Sant Tukaram Nagar, Pimpri, Pune, (India).

***Corresponding Author: Sanchita Choubey**

Department of Microbiology Dr. D. Y. Patil Arts, Commerce and Science College, Sant Tukaram Nagar, Pimpri, Pune (India).

Article Received on 07/07/2017 **Article Revised on 27/07/2017** **Article Accepted on 17/08/2017**

ABSTRACT

Increasing demand of cosmetics all over the world from teens to adults has increased awareness related to safety issue. The objective of this paper is to review the methods that are commonly employed in the cosmetic and personal care products to ensure the microbiological safety of the products. This paper also reviews the research carried out on establishing the microbiological quality testing of various categories of cosmetics products such as Talcum powder, hair care products, creams and lotions, eye cosmetics, lipsticks, etc. Microbial contamination of cosmetics poses a great problem to the Cosmetics manufacturing process, especially from an economic point of view. Cosmetic products need not to be sterile but may contain low levels of microbial load during use. Commercial cosmetic products have been found to be responsible for serious overt and covert skin infections, which were often ignored as the sources or vehicles of transmission of pathogens. Microbial contamination of cosmetic products is very crucial because of their daily use and direct contact with the skin. These products are at high risk for microbial contamination from various sources such as environment, consumer's hands, and body sweat and during the time of manufacturing. Therefore, good manufacturing practices (GMP) and hygiene must be carried out by manufacturers and personnel, cosmetic products should be stored in an aseptic environment to avoid contamination before vending in the markets. The pharmaceutical manufacturer should assure that product-specific knowledge and expertise are available for the development of an effective HACCP plan.

KEYWORDS: Commercial products, cosmetic, bacteria, Microbiology, Safety testing, Formulation.

INTRODUCTION

The field of cosmetics and microbiology had not come into contact much before the 1930s and cosmetic microbiology became more important in 1940s. According to the Association of Southeast Asian Nations (ASEAN), cosmetics are defined as any substance or preparation intended to be placed in contact with the external parts of the human with a view exclusively or mainly for cleaning them, perfuming them, changing their appearance, and/or correcting body odors and/or protecting or keeping them in good condition.[1] The US Food, Drug and Cosmetic Act defines cosmetics as articles intended to be rubbed, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, while maintaining the structure and functions.[2] Included in this definition are products such as skin creams, lotions, perfumes, lipsticks, eye and facial make-up preparations, hair straighteners, conditioners, shampoos, permanent waves, hair colours, and deodorants. The US FDA and the EU Cosmetics Directive requires that the microbial population be low, stable and devoid of harmful organisms, particularly in products designed to be applied around the eye and other sensitive areas, or for use by babies, young children, the elderly, and the immune compromised.[3]

The microbiology technical committee in charge of cosmetic products at the international Standardization organization (ISO/TC217) has come up with guidelines on GMP.[4] These guidelines are designed to cover various quality aspects of cosmetics, including production, documentation and specific cleaning procedures. The guidelines also cover microbiological control of raw materials, bulk and finish products, packaging material, personnel, equipment and storage areas.

Many cosmetic products currently available in the market are in the form of gel. Most of these preparations are basically aqueous and contain carboxy- vinylpolymer which thickens upon the addition of alkali.[5,6] They also

contain a variety of ingredients to provide the product with required functional properties. The pH of such products is typically within a degree on either sides of neutrality and marketed brands are stored by consumers at room temperature or in slightly warmer places.[7] Thus, physical and chemical factors required for microbial growth are all fulfilled by the environment of gel formulations.

Many present-day skin moisturizing creams and lotions contain special additives like plant extracts, fatty acids and vitamins. As these additives could serve as nutrients for microorganisms, it is possible that such products may get contaminated and be vehicles of pathogen transfer. There are some reports of bacteriological profile of cosmetics from temperate countries.[8,9,10] The predominance of gram-negative bacteria may be due to the greater ability of these organisms to survive and multiply in creams and lotions than gram-positive bacteria.

Microbiological contamination in a product can originate from one of two sources: Contamination during production and filling: or from entering the product via the consumer when the product is being used. From the moment the packaging is broken open up to the complete consumption of the product, various microbiological contamination is continually introduced from the environment and from the consumer themselves (hands, body). Possible impurities during the production and filling processes will be tested by regular routine microbiological controls of the batches. Bacteria getting into the product while it is being used are confronted by the use of preservatives. Contamination of microorganisms in cosmetics may cause spoilage of the product and when pathogenic, they represent a serious health risk for consumers. Most of the cosmetics are not sterile and they are made of non-sterile raw material. Although cosmetics do not have to be sterile, limit values have been reported according to the type of the cosmetics. The ability of microorganisms to grow and reproduce in cosmetic products has been known for many years.[11]

Following are the cosmetic products used by men and women, which need to be microbiologically safe.

Talcum powders are cosmetic product used all over the world to prevent rashes and keep skin free of moisture. Creams are external preparations, usually for application to the skin. Creams may be considered as pharmaceutical products, as even cosmetic creams are based on techniques developed by pharmacy. Creamsare liable to microbial contaminations either in the course of their preparation, transportation and/or accidentally, during use by the consumers which may lead to their spoilage. Body lotions are a low viscosity topical preparation intended for application to unbroken skin. Hair straightened otherwise known as ‘‘relaxer’’ is a type of lotion or cream generally used by people with "afro textured hair", to make hair less curly, easier to straighten or to create perms by chemically "relaxing" the natural curls by breaking down the proteins bonds of hair, temporarily or permanently. Cosmetic eye preparations are liable to microbial contamination either in the course of their preparation, by the personnel, storage environment, during transportation and/or use by the consumers which may lead to their spoilage.Lipsticks fall under the face care cosmetics category and are composed of waxes, oils, emollients, emulsifiers, pigments/colourants, and binders in varying concentrations, which determine the characteristics of final products. Product contamination may arise from raw materials or water used in formulation. This spoilage may lead to alteration in organoleptic properties of creams which may manifest in terms of changes in color, odor and/or taste; as well asbiodegradation of active constituent of such creams. The growth of bacteria that produces alcohols or degrades emulsifiers may lead to instability, splitting of the emulsion and eventual spoilage. Microbial growth can produce enzymes that cause degradation of active ingredients and changes in the pH.

This paper reviews the methods for evaluation of microbiological safety of the cosmetic products, the guidelines governing the Quality of the products and the research findings of studies conducted to evaluate the microbiological safety of the various types of cosmetic products available in markets.

Methods for evaluation of Microbiological quality of cosmetic products

Evaluation Test

For determination of total bacterial and fungal (mold and yeast) counts, ten grams/ml of each cosmetic sample isaseptically suspended with 100 ml of sterile soybean-casein digest broth medium, in presence of tween 80, and shaken well for 15 min, at room temperature. Aliquots, 0.5 ml, of the original samples and their serial dilutions up to 10^{-2} are spread-plated, in duplicate, onto the surface of soybean-casein digest agar medium for isolation of bacteria and incubating for 24 - 48 hour at 30-35±2^{0}C.For isolation of fungi, Sabouraud's dextrose agar medium was used and incubated at20-25±^{0} C for 5 days.[12]

Identification of Bacterial Isolates

All bacterial isolates are identified based on their Gram reaction and biochemical tests namely, Indole test, Catalase test, Coagulase test, Methyl –red test, Voges – Proskauer test, Oxidase test, Sugar fermentation as described by U.S.FDA manual online.[13,14]

Identification of fungal Isolates

All fungal isolates are identified based on their macroscopic and microscopic appearance with reference to manuals of.[15,16]

Detection of Pathogenic Bacteria

For detection of pathogens in cosmetics samples the tests for detection of *E.coli, Pseudomonas, Staphylococcus aureus* and *Salmonella* are performed according to the guidelines given by. [17]

Ten gram of cosmetic samples are aseptically suspended in 100 ml of lactose broth medium, shaken well for 15 min at room temperature, and incubated for 24h at 37 ±2°C. After incubation, loopful of the original suspensions are streaked on MacConkey, Levine eosin – methylene blue, and triple sugar iron agar media tubes to detect *Escherichia coli*, and on plates containing bismuth brilliant green, xylose – lysine desoxycolate, and triple sugar – iron agar media tubes to detect *Salmonella spp.* Moreover loopful of suspensions are streaked on plates of Vogel-Johnson, mannitol–salt and Baird-Parker agar media for detection of *Staphylococcus spp.* The conformation tests for detection of *Staphylococcus aureus* is done using blood agar medium and coagulant test. The plates of cetrimide agar medium and *Pesudomonas* isolation agar media are used to detect *Pseudomonas aeruginosa.* The fungal plates are incubated at 28 °C for 5–7 days, and the bacterial plates are incubated at 37 °C for 24-48 hrs. The bacterial isolates are picked up, purified and subcultured for further identification. The bacterial isolates are identified using Gram staining, oxidation fermentation test, oxidase, and catalase tests as described in the Bergey's Manual of Systematic Bacteriology.[18]

Antibiotic Test

Antibiotic susceptibility tests are performed against the isolates obtained from the cosmetics samples according to the methods described by NCCLS standards.[19] In this method, Muller-Hilton Agar plates are inoculated with the isolated skin flora and discs containing 50 µl suspensions made from of the skin care product samples (fairness cream, deodorant and talcum-powder) areplaced. Developed zones of inhibition are recorded after 18 hours of plate's incubation at 35 ºC.The plates are observed for the Antimicrobial activity of personal care products on skin flora. Interpretation of susceptibility test results carried out according to standard sensitivity tables by the NCCLS. Isolates with zones of inhibitions that came within the intermediate reading for a particular antibiotic are considered as resistant.

Challenge Test for Preservative Capacity

Bacteria getting into the product while it is being used are confronted by the use of preservatives. The effectiveness of preservatives can be tested and verified by testing for a sufficient level of preservation as part of a so-called microbiological challenge test. The requirements are dependent upon the intended purpose of the product. For the microbiological challenge tests, the products are inoculated with germs and germ reduction is investigated at regular intervals over a specified period of time. [20] The challenge test used is a modification of the standard Cosmetics, Toiletries, and Fragrance Association procedure.[13]

In practice, the use of single, pure culture inocula for challenge testing is mostly done for qualitative and quantitative reasons. It is very convenient to determine which microbial strains are having an issue during a challenge test and to calculate either the percentage or log reduction for each of the challenge test microorganisms. For most preservative challenge test methods, the concentration of microorganisms in test samples after inoculation ranges from 10^5 to 10^6 colony forming units (CFU)/g or mL of test sample. This concentration of microorganisms is higher than what would be normally expected to occur during normal consumer usage of a product formulation. The main reason for using this high number of microorganisms in challenge test samples is to determine if the preservative system can handle a gross microbial insult or abuse to separate the inadequate from the adequately preserved formulations by obtaining the necessary 99.9% or 3-log reduction in viable CFU. By using a lower concentration of microorganisms in challenge test samples (e.g., 10^2–10^3 CFU/g or mL), it would be more difficult to measure the amount of reduction in viable microorganisms due to the antimicrobial activity of the preservative system unless the test criterion for preservative adequacy is stasis.

The USP method is by far one of the most recognized preservative efficacy testing methods in use. ATCC test organisms are used in this method and the organisms used are *C. Albicans*(ATCC 10231), *A. niger* (ATCC 16404), *E. coli* (ATCC 8739), *P. aeruginosa* (ATCC 9027), and *S. aureus* (ATCC 6538). The bacterial test organisms are grown on Trypticase Soy Agar and the fungi are grown on Sabouraud Dextrose Agar. The mold inoculum preparation uses saline with 0.05% polysorbate 80, while the rest of the organisms are diluted in saline. The inocula levels for each organism should not exceed 1%, and the counts should be in the range of 1.010^5 to 1.010^7 CFU/mL. The plating media used in this method are Trypticase Soy Agar for the bacteria and Sabouraud Dextrose Agar for the fungi. The plating diluent must have a preservative neutralizing agent. Conventional plating dilutions of 1:10 to 1:10,000 are used when sampling. The sampling time points for the USP method are at time 0, 14, and 28 days. The bacterial samples are incubated at 32.5±2.5ºC for three to five days. The yeast samples are incubated at 22.5±2.5ºC for three to five days, and the mold samples are incubated at 22.5±2.5º C for three to seven days. There is no rechallenge in the USP. [20]

In-Use Test[21]

Ten grams of product is diluted in 90 ml of sterile double-reverseosmosis water and thoroughly mixed, and 0.5 ml of the diluted product is pour plated with 10 ml of Trypticase soy agar with 1.5% Tween80. Plates are incubated at 30 to 35°C ± 2, for 3 days followed by 20 to

25°C ± 2 for 2 days. A product is considered contaminated if >100 CFU/g is observed or if gram-negative bacteria at any level are detected at initial receipt and 4 to 7 days post receipt.

Microbiological Qualities of Cosmetics

Hair care products

The samples are qualitatively examined for the presence of some potential pathogens. The bacterial contaminants found in most of the hair care products are *S. aureus, Pseudomonas spp. and Bacillus spp.,* as shown in table 1.

No fungal contamination detected in all brands of hair care products.The total bacterial counts detected as CFU/g or mL, in shampoo 3 x 10^4 - 14 x 10^5, Hair styling gel 1.13 x 10^2 - 2 x 10^5, Hair oil 27-34, Hair straightener 3.5 x 10^2-7.7 x 10^2.

Most of the cosmetic products with high water content (moisture) were at a risk of being contaminated by microorganisms, and consequently may be altered their composition or pose a health risk to the consumer.[22,23,24]

Table 1: Microbiological quality of Hair Care Products.

Contaminated Product	Microorganisms	Bacteria CFU/g	References
Shampoo[25,26]	*Pseudomonas spp., E. Coli*	3x10^4 - 14 x 10^5	
Hair conditioner[25]	*S. aureus, Yeast, Coag–ve Staphylococci*	1.13 x 10^2 - 2 x 10^5	
Hair styling gel[25,26]	*S. aureus, Enterobacter spp., Micrococcus spp., Pseudomonas spp., Serratia spp.*	46 - 98	
Hair groom[25,26]	*Alcaligenes spp., Coag–ve staphylococci, Pseudomonas spp., Bacillus spp*	1.23 x 10^2 - 1.8 x 10^4	
Hair repair emulsion[25,26]	*Yeast, Pseudomonas spp., Alcaligenes spp., Bacillus spp.*	27-34 CFU/g	25.Qasem M. Abu Shaqra, Rania M. Al Groom (2012)
Hair oil[26]	Erwinia amylovora, Serrati arubidaea, Bacillus licheniformis, Buttiauxella agrestis, Pseudomonas putida	3.5x10^2-7.7x10^2	26.T. H. Elmorsy and E. A. Hafez (2016)
Hair straightener (Relaxer)[27]			27.Michael Oluyemi Babalola1 and Mary Eze (2015)

Body lotions and body creams

The bacterial contaminants found in most of the hair care products are *Enterobacter spp., Pseudomonas spp., Micrococcus spp. and Bacillus spp.,* as shown in table 2.

No fungal contamination detected in all brands of lotions& creams products. The total bacterial counts detected in Baby lotion3.5 x 10^2-4.5 x10^2.

Table 2: MicrobiologicalqualityofBody lotions and body creams.

Contaminated Product	Microorganisms	Bacteria CFU/g	References
Body lotion[25]	*Bacillus spp., Coag–ve Staphylococci, Pseudomonas spp., Enterobacter spp., Micrococcus spp.*	- -	
Hand & body cream[25]	*Bacillus spp., Pseudomonas spp., Enterobacter spp., Coag–ve Staphylococci, Micrococcus spp.*	3.5x10^2-4.5x10^2	25.Qasem M. Abu Shaqra, Rania M. Al Groom (2012)
Baby lotion[27]	*Erwinia amylovora, Serratia marcescens, Staphylococcus lactis, Enterobacter gergoviae, Erwinia amylovora, Bacillus subtilis, Enterobacter gergoviae, P. Aeruginosa, Enterobacter cloacae, Erwinia amylovora*		27.Michael Oluyemi Babalola1 and Mary Eze (2015)

Face creams

Cosmetic creams could harbor a high number of bacteria and fungi including hazardous type such as: *Staphylococcusspp.,Enterobacter spp., Pseudomonas spp.,Micrococcus spp., Bacillus spp.,and Candida spp.*as shown in table 3. The total bacterial counts detected in Face cream 1.0 x 10^2- 6.5×10^3. The total fungal count detected in Face cream1.0 x 10^2 - 3.5×10^4, Foundation creams 1.0 x 10^2- 3.0 x 10^3, Bleaching creams 3.0 x 10-1.0 x 10^4. The results presented in some of the research papers show that the preservatives employed in these cosmetic products did not possibly possess adequate preservative capacity to be able to bring about acceptable low levels of microbial contamination as demanded by

regulatory bodies.[28] There is therefore, a pressing need to search for compounds with such additional properties if the microbiological wholesomeness of such products is to be ensured.

Also, Baird[8], reported that 32.7%; of the tested creams were having great number of microorganisms. The high fungal contamination of some cosmetic creams may be attributed to that products are often water in oil emulsions with high concentrations of solutes and lowered water activity.

Table 3: Microbiological qualityof Face creams.

Contaminated Product	Microorganisms	CFU/g		References
		Bacteria	Fungi	
Peeling cream [25]	*Bacillus spp., Pseudomonas spp., Enterobacter spp.,Coag–ve Staphylococci, Micrococcus spp.*	- -	- -	25. Qasem M. Abu Shaqra, Rania M. Al Groom (2012)
Face cream[29,30,31,32]	*Staphylococcus aureus, E.coli, Enterobacter spp.*	1.0×10^{3} – 6.5×10^{3}	2.0×10^{3} - 3.5×10^{4}	29. Nisha Garami Rohinee Patle, Anita Chandak (2016)
	Staphylococcus aureus, Bacillus spp.,Staphylococci coag-ve, Trichophyton spp.,Asp. Fumigatus, Penicillin spp., Microsporium canis, Mucor spp.	1.0 X 10^2- 8.0 X 10^2 -	1.0 X 10^2 -	30. Peter G Hugbo, Anthony O Onyekweli and IjomaIgwe (2003)
Foundation creams[31]	*Pseudomonas aeruginosae, Staphylococcus epidermidis, Candida spp., Alternaria spp., Clostridium perfringens*	1.0 X 10^2- 3.0 X 10^3	1.0 X 10^2- 3.0 X 10^3	31. Gamal M. A. B, AboAzza M. M., Al Gayeed A. O. A And Sawan M. S.(2015)
Bleaching creams[31]	*Pseudomonas aeruginosa, Candida parapsilosis, Serratia liquefaciens* *Staphylococcus aureus, Rhizopus spp., Aspergillus spp.,Clostridium perfringens* *Bacillus subtilis, Penicillum spp., Fusariumspp*	4.0 X 10^2- 2.0 X 10^4	3.0 X 10- 1.0 X 10^4	32.Angela Budecka, Alina Kunicka-Styczyńska (2014)

Talcum Powders

The frequency of occurrence of bacteria in the total sample shows that all the samples are contaminated with bacteria and fungi which indicating that talcum powders can permit the growth of bacteria. Bacterial isolates from powder are *Staphylococcus spp., Bacillus spp., Aspergillus spp., Penicillium spp. and Rhizopus spp.* The adult powders and the baby powders both are highly contaminated with bacteria and fungus shown in table 4.

Table 4: Microbiological qualityofTalcum Powders.

Contaminated Product	Microorganisms	CFU/g		References
		Bacteria	Fungi	
Baby powders[33]	*Staphylococcus spp., Bacillus spp., Streptococcus spp., Micrococcus spp., Escherichia coli, Aspergillus spp., Rhizopus spp., Candida spp.,Trichoderma spp., Penicillium spp.*	4.90x 10^8-1.37 x 10^9	1.5 x 10^5-6.0 x 10^5	33.Omorodion, Nnenna J.P, Ezediokpu Marycollete,N Edward Grant (2014)
Adult powders[33,34]	*Staphylococcus spp., Bacillus spp., Streptococcus spp. and Micrococcus spp., Aspergillus spp., Rhizopus spp., Candida spp., Penicillium spp. and Trichoderma spp.*	3.50x 10^8-9.75 x 10^8	1.5 x 10^5-6.0 x 10^5	34.Wahla V, Kasana M (2015)

Eye cosmetics

Eye cosmetics contaminated with bacteria and fungi in varying degrees including *Staphylococcus epidermidis, Bacillus subtilis, Penicillium spp.* The colony counts of all detected bacteria are ranging from 2.0 x 10^2-9.0 x 10^2 in Eye shadows, 2.0 x 10^2-2.0 x 10^3 in Mascara, 2.0 x 10^2-2.0 x10^3 in Eye liner and fungi are ranging from 1.0 x 10^1-3.0 x10^1 in Eye shadows, 1.0 x 10^3 in Mascara, and 1.0 x 10^2 in Eye liner.

Table 5: Microbiological qualityofEye cosmetic.

Contaminated Product	Microorganisms	CFU/g		References
		Bacteria	Fungi	
Eye shadows[35]	*Bacillus subtilis, Staphylococcus epidermidis, Alternaria spp., Penicillium spp.*	2.0 x10^2-9.0 x10^2	1.0 x10^1 -3.0 x10^1	35.Tamalli M, M A
Mascara[35]	*Bacillus subtilis, Aspergillus spp., Staphylococcus epidermidis,*	2.0 x10^2-2.0 x10^3	1.0 x10^3	B Gamal, M A
Eye liner[35]	*Staphylococcus epidermidis, Bacillus subtilis, Penicillium spp.*	2.0 x10^2-2.0 x10^3	1.0 x10^2	Alghazal(2015)

Lipsticks & Lip gloss

Pseudomonas spp.andStaphylococcus spp. is commonly found in Lipsticks & Lip gloss. *Staphylococcus* and *Pseudomonas* species is alarming and calls for stringent means of testing and analyzing of lipsticks by the regulatory agencies.

Table 6: Microbiological qualityofLipsticks & Lip gloss.

Contaminated Product	Microorganisms	Bacteria CFU/g	References
Lipsticks[27,36]	*Pseudomonas spp., Proteus, Providencia Morganella , Staphylococcus spp.,*	-	27.Michael Oluyemi Babalola and Mary Eze (2015)
Lip gloss[27,36]	*Streptococcus lactis, Klebsialla pneumonia, Staphylococcus aureus, Bacillus licheniformis, Bacillus cereus,*	20 x10^2– 38x10^2	36. Sneha Sunil Sawant and Varsha Kelkar-Mane (2015)
	Enterobacter spp, Erwinia carotovora, Micrococcus luteus, Escherichia shermanni		

CONCLUSION

Cosmetics can be contaminated with microorganisms when they are not preserved properly. Contamination of microorganism in cosmetics may cause spoilage of the product and pathogenic, they represent a serious health risk. Most of the cosmetics are not sterile and they are made of non-sterile raw material. Although cosmetics do not have to be sterile, limit values have been reported according to the type of the cosmetics.[37]

Contamination of microorganisms in cosmetics may cause spoilage of the product and when pathogenic, they represent a serious health risk. Microorganisms that

should not be allowed to be found in cosmetic preparations are; *Staphylococcus aureus*, *Escherichia coli*, *Salmonella spp.*, *Candida albicans*, *Clostridium spp*., and *Pseudomonas aeruginosa*. Since 1960s, opportunist organisms, such as *Klebsiella pneumoniae, Pseudomonas aeruginosa, Pseudomonas sp., Serratia sp. and Enterobacter sp.*, have been isolated from cosmetic products to a certain extent. [38] FDA stated it is not necessary for cosmetic products to be sterile, however, they must not be contaminated with pathogenic microorganisms and the density of non-pathogenic microorganisms should also be low. Based on the FDA guidelines, cosmetic products must be completely free of high-virulence microbial pathogens, and the total count of aerobic microorganisms per gram must be low. There are no widely acceptable standard for total microbial counts. Based on International Microbiological Standard, recommended limit for bacteria contaminants in cosmetic products is that the total count should not be greater than 500 CFU/g for an eye-area product and for non-eye area products, counts should not be greater than 1.0×10^3 CFU/g for bacteria, 1.0×10^2 CFU/g for molds and 0 CFU/g of coliform at the time they reach the consumer.[39,40]

Frequency of use, applying method and storage conditions could highly affect the risk of microbial contamination of the products. [23, 41, 42] Microbial contaminants may originate during the manufacturing processes, particularly from the raw materials, and/or during the use of the products by the consumer. Since a product is opened, it may further contaminate by consumer hands and/or environmentContamination of cosmetic products may directly affect the human health as a result of formation of harmful microbial metabolites and spoilage of the productsTherefore, microbial preservation of cosmetics is of essential to ensure the consumers safety and maintenance of the hygienic level of the products.[24,43,44] Evidence of microbial contamination and spoilage. Microbial contamination of cosmetics renders them unfit for use as the products may develop various degrees of aesthetic changes.The approaches adopted herein are simple, easy to perform and can become part of the routine work in the microbiological quality control of cosmetics.

Good Manufacturing Practice (GMP) should be strengthened, the efficacy, and continued use of the adopted preservatives should be reviewed, to ensure wholesomeness of the products through their shelf life, Good manufacturing practices and hygiene must be carried out by manufacturers and personnel. Water must be tested continuously for microbial growth. It might be necessary to sterilize deionized water to obtain a sufficient purity. Raw materials should be tested before use especially those of natural origin. Cosmetic products should be stored in a clean environment to avoid contamination. It is necessary to reassess production processes to ensure that techniques capable of reducing microbial contaminations are employed.[33] Microbial contamination, from manufacturer to consumer, can be controlled by sanitary processing and using appropriate and adequate preservatives.

The principles of good manufacturing practice must always be followed and raw materials, particularly those of natural origin, must be tested for contamination before use and limits of acceptability established. Areas where contamination may be introduced must be identified and controlled. Due to GMP, contamination during actual production is of such a low order that modern cosmetics manufacturing plants can achieve" absence of microorganisms in almost 100% of units produced". Manufactures also aim, wherever possible, to develop formulations which are incapable of microbial growth. The level of microbial contamination in a non-sterile product such as, cosmetics formulations, is made clear in the microbial limit standards which should be maintained in the products during their use, in spite of the inevitable contamination by the users, through the addition of a suitable preservative in the products which guarantees the control of microbial growth even before they are marketed. Cosmetic product are used all over the world and, although aiming at the same high level of consumer protection, their regulations and requirementsare quite different from one part of the globe to another. Contaminating microorganisms in cosmetic may cause spoilage of the product and represent a serious health risk for consumers.[39]

Therefore, the need to control microbiological contamination of products has been of considerable concern to manufacturer. Modern pharmaceutical, cosmetics and toiletries strive for high microbiological standards to protect their products from spoilage on the hand, and their consumers from infection, on the other hand unlike foodstuffs, which are usually kept refrigerated (or thrown away after a few days); a much longer shelf life is expected of personal care products.[45] The European Scientific Committee on Consumer Safety in 2010 concluded that the levels of propyl and butyl parabens in cosmetics should be reduced to 0.19% i.e 1900 ppm when used individually or combined for them to be safe for the health of the consumers (Cosmetic Ingredient Report 2012).[46]

Microbial contamination of cosmetic products is a matter of a great importance to the industry and it can become a major cause of both product and economic losses. The need of the microbial quality of cosmetics is well-clarified and wel1-recognized.The distribution of microbial contamination between different brands of each class of preparations may reflect one or more of several factors including good manufacturing practice of the manufacturer’s post-process contamination, inadequate preservation, extended storage by the retailer etc. The frequency of occurrence of bacteria in many of examined sample shows that most samples are contaminated with bacteria.

The cosmetic industry has many compelling reasons to establish and maintain Microbiological quality of its products. As these rarely produced under a sterile conditions, appropriate control of the many factors involved in the microbiology of the products is critical. These factors include raw material quality, hygiene and training of manufacturing personal, establishment of sanitary design and materials, application of validated cleaning and sanitization process design and control, application of general chemical/physical factors including heat, time temperature, and pH addition of specific chemical preservation and use of appropriate barrier packaging. All of these factors are effective for the control of microbiological risks in the cosmetic products.The need to control microbiological contamination of products has been of considerable concern to cosmetic manufacturer.

The following diagram represents the CCPs where the cosmetic products may get microbial contamination.

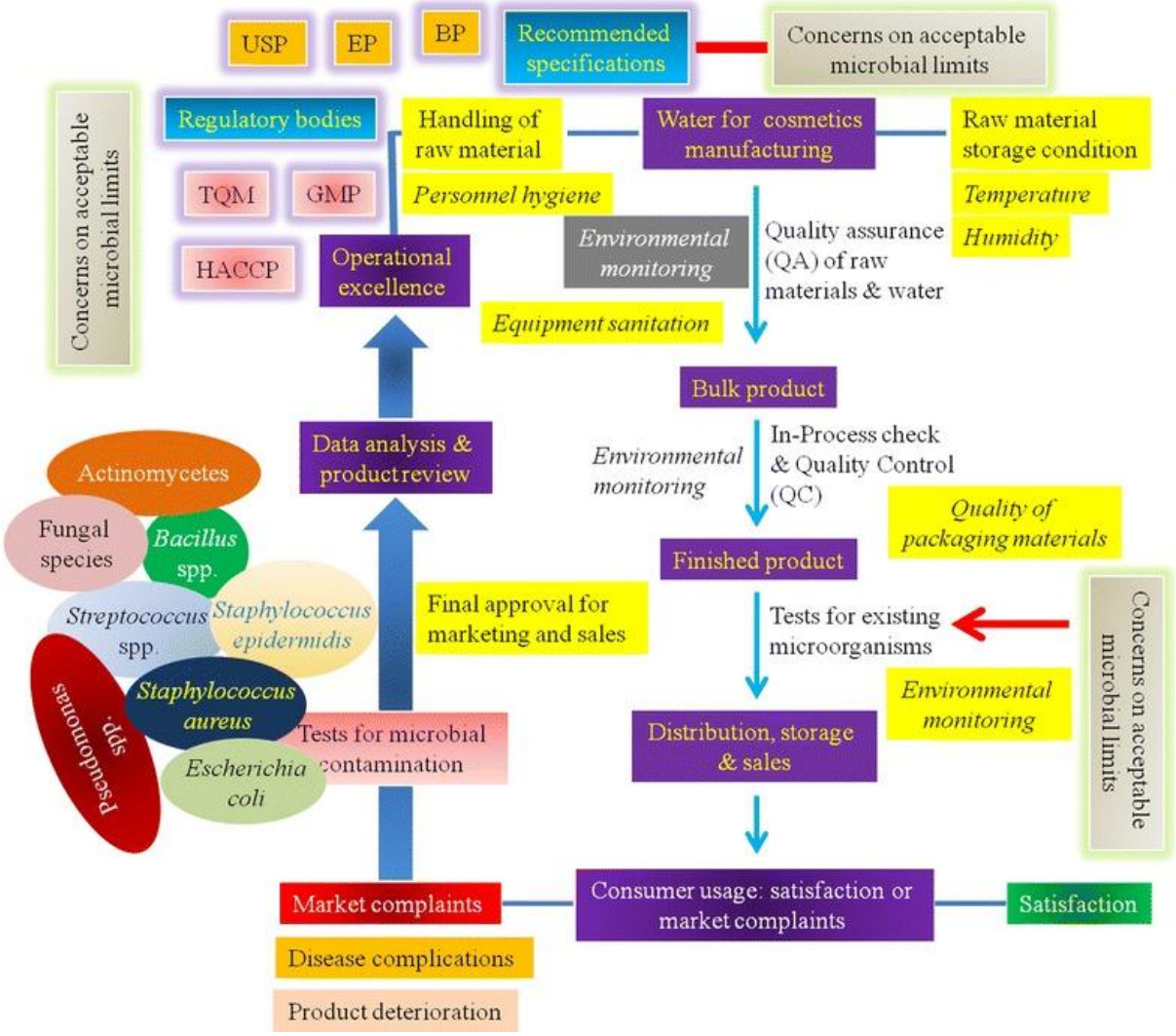

Fig 1: Regulatory Scheme for Maintenance of the Microbiological Quality of Cosmetic Products (Source: Noor et.al. 2015).[47]

In each stage of the manufacture and supply of pharmaceuticals/ cosmetics, the necessary conditions should be provided and met to protect the pharmaceuticals concerned. This has traditionally been accomplished through the application of Good Clinical Practice (GCP), Good Laboratory Practice (GLP), GMP and other guidelines, which are considered to be essential to the development and implementation of effective HACCP plans. HACCP plans are focused on hazards, the overall objective being to ensure that pharmaceuticals are safe for use. The existence and effectiveness of GCP, GLP and GMP should be assessed when drawing up HACCP plans. In developing specific training to support a HACCP plan, working instructions and procedures should be drawn up which define the tasks of the operating personnel to be stationed at each critical control point. Specific training should be provided in the tasks of employees monitoring each CCP.[48] Cooperation between producers, traders and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industrial staff and the control authorities to encourage and maintain a continuous

dialogue and create a climate of understanding in the practical application of HACCP. The success of a HACCP system depends on educating and training management and employees in the importance of their role in producing safe pharmaceuticals. Information should also be provided on the control of hazards at all stages of production and supply. Employees must understand what HACCP is, learn the skills necessary to make it function properly, and must also be given the materials and equipment necessary to control the CCPs.

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