





DEPARTMENT OF PHARMACEUTICS

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Scintilla is the quarterly E-news letter of Department of Pharmaceutics, FPH, RUAS which seeks to provide to world outside, News, Views, and Creative expressions from the members of the department. Scintilla comes directly from Latin, where it carries the meaning of "spark" - that is, a bright flash such as you might see from a burning ember or spark of specified quality or feeling, which is almost synonymous to department's intent, hence the name Scintilla

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SCINTILLA

EDITORIAL

Hello Readers!!

Happy new year to our readership, contributors and to all members of the editorial team. I wish everyone a healthy, happy and prosperous 2022.

Firstly, my heartfelt congratulations to all the contributors of this current edition of Scintilla. Seeing the variety of articles with a broad coverage on cosmeceuticals is quite gratifying. The technology never stands still. It keeps rolling and emerges in different forms to meet the demands of the real world. Likewise, cosmetic technology is constantly evolving. Certainly, great progress has already been made in this field to provide high end products with exceptional features. As I fervently desire to keep the readers abreast of the advanced developments in the pharmaceutical sector, the forthcoming issues will present the latest developments in the pharmaceutical field.

The editorial team loves to experiment with changes in the news letter format and will make relevant changes from the next issue onwards for a more enjoyable and better reading experience. My earnest appeal to all the prospective contributors to make best use of this platform for showcasing their intellectual interests.

It is our pleasure to encourage and support rightful structuring and submission of articles in the prescribed form with in the due date for timely release of the coming issue. Do feel to contact the editorial team for any assistance.

Scintilla looks forward to our continued collaboration in 2022 and beyond.

Open-mindedly, I am seeking valuable suggestions from all quarters for bettering Scintilla.

Do remember that life is short, time is fast; no replay, no rewind. Enjoy every moment as it comes.

Last but not the least, protect yourself and protect others.

Stay safe and stay healthy.

Cheers.



Dr. S. Bharath
Chief Editor

HAPPY NEW YEAR



Praying that you and your family have a happy and healthy New Year!

Chief Editor Scintilla



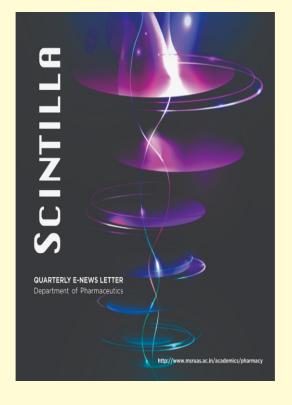


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Theme for Next Vol. 2, 2 nd Issue (Apr-Jun 22)

CURRENT TRENDS IN PHARMACEUTICAL FORMULATION TECHNOLOGY

Inviting:
Best Article (3000 words)

There are surprising prizes to be won !!! (submit before May 30th, 2021) HURRY !!!! Submit your entries, queries and/or feedback to

- 1. Executive Editor, bvbasu@gmail.com
- 2. Layout Editor , krdarsh18@gmail.com





DEPARTMENTAL PRIDE

Publications Update

- I. Tanmoy Ghosh, R. Deveswaran, S Bharath. Development and characterization of copper cross-linked freeze dried bioscaffolds for potential wound healing activity. Journal of pharmaceutical innovation. (Accepted) (Springer)
- 2. Tanmoy Ghosh, R. Deveswaran, S Bharath. Copper crosslinked carboxymethyl chitosangelatin scaffolds: A potential antibacterial and cytocompatible material for biomedical applications. Materials Today: Proceedings. https://doi.org/10.1016/j.matpr.2021.10.140. (Elsevier)
- 3. Thimmasetty J, Shashank NN, Abdul Raheem T, Shwetha SKK, Tanmoy G. Modafinil Cocrystals for Altered Physicochemical Properties. Research J. Pharm. and Tech. 2021; 14(9): 4891-96. 10.52711/0974-360X.2021.00850 (Scopus)

Conference Presentation

- I. Tanmoy Ghosh, R. Deveswaran, S Bharath. Copper crosslinked carboxymethyl chitosangelatin scaffolds: A potential antibacterial and cyto-compatible material for biomedical applications. The 2021 Third International Conference on Recent Advances in Materials and Manufacturing (ICRAMM 2021) organized by Department of Mechanical Engineering, D Y Patil College of Engineering and Technology, Kolhapur.
- 2. Dr.B V Basavaraj presented a poster in the Bangalore Tech Summit 2021 held on 17-19, November 2021.
- 3.Mrs. Shwetha K presented a poster in the Bangalore Tech Summit 2021 held on 17-19, November

National Conference Participation

Dr. B V Basavaraj attended National Conference on Implementation of NEP 2020: Challenges and Opportunities for Educational Institutions organized by EPSI, 30th November 2021, Bangalore

Certification Courses

Dr B V Basavaraj completed online certification course on Product Management from TURNIP, Dec 2021





UPCOMING EVENTS







DEPARTMENT OF PHARMACEUTICS FACULTY OF PHARMACY

Cordially invite you to attend the Guest

JOURNEY OF PHARMA RESEARCH FROM INSTITUTE TO INDUSTRY: CURRENT SCENARIO

Dr .KOTAMBALLI N CHIDAMBARA MURTHY
M. Pharma, PhD, DR&D, MNAMS

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Dr. Kotamballi N Chidambara Murthy has an industry experience of 17 years (India-12 Years; USA-5 Years) Principal Scientist- Ramaiah Medical College, Bengaluru, India .Postdoctoral Research Scientist and Associate-Texas A&M University, USA ,Senior Research Fellow-CSIR-Central Food & Technological Research Institute, India. His technical skills include Phytomedicine, Molecular Pharmacology Nutraceutical, Academic councilor, Research trainer, Research mentor, Scientific writing and Grant writing trainer etc. He has received several awards (Dr. V.N. Patwardhan Prize-2012–ICMR-Govt., of India, MNAMS-NAMS, New Delhi, Research Publication Award-2014, Govt., of Karnataka, SS Mishra Memorial Award – NAMS, New Delhi, Best paper award-62nd Indian Pharmaceutical Congress) from organizations for his contribution to research.

Date: 26 th Feb 2022 Time: 11.00 AM – 12.30 PM Event Platform: MS Teams

Event Link: https://tinyurl.com/sjbzkhjw







COSMECEUTICALS: THE BEAUTY OF MEDICINE!

Darshan K R

IV Pharm D



biologically active ingredients purporting to have medical or drug like effects. They are generally intended of wellbeing and excellence of the skin.Dr. Albert M Kligman coined the term "Cosmeceuticals" in 1984 as a way to define a skincare product that ensures additional care than a cosmetic but is rather not a drug. It's a combination of the words cosmetic and pharmaceutical .The FD & C act doesn't recognise the term "Cosmeceuticals".



Fig (1): Dr. Albert M Kligman, University of Pennsylvania, Professor emeritus- the father of retinoid- based acne treatments

Consumer demand for products that keep them looking young and faultless has improved cosmeceutical research and development as well as its corresponding sales volume. Many cosmetic

compounds that were previously thought to be harmless are shown to modify dermatological conditions moving past standard beauty care products which just momentarily upgrade the skin. Cosmeceuticals effect biomedical transformation and enhance the restorative property of the skin. Since these items are not intended to upgrade or to treat skin disorders, they have forestalled drug rules and investigation. Subsequently, 'cosmeceuticals' obscure the line among medication and restorative, clinical specialist and aesthetician and impacted individual or shopper.

Customers struggle with the selection of new beauty products and are unsatisfied when the product fails to provide its claimed benefit, and will revert to doctors' advice in selecting the best product from the market. The "cosmeceutical doctors" can help in selecting the product either by genuine results with proof or by noticing the predictable side effects, based on their experience. Although there is a popular consensus among skincare specialists as to know what constitutes a cosmeceutical, there is no regulatory framework defining these products. Like cosmetics, the cosmeceuticals doesn't require rigorous testing due to absence of standard guidelines.



Fig(2): Cosmetic products





According to the US FDA, cosmeceuticals are cosmetics or OTC drugs relying on the claims that product makes. Drugs can treat a problem like wrinkles and acne but the beauty product can improve, minimizes, or softens wrinkles however it cannot claim to treat the condition. Manufacturers can get the product on to the market quickly, and a lot less expensively. Cosmeceutical claims are purposely left vague to preserve their advertising and marketing strategy. Cosmeceutical healthy skin care ingredients are found to penetrate better into the skin surface. The 500-Dalton rule states that for a substance to be able to cross the skin barrier, it must have a molecular weight of fewer than 500 Daltons. Though there are certain exceptions to this rule, it is generally considered as a standard rule of thumb for cosmetic manufacturers.

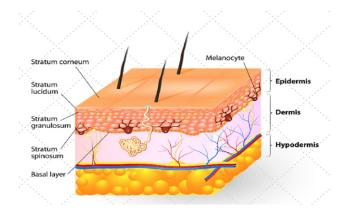


Fig (3): Layers of skin

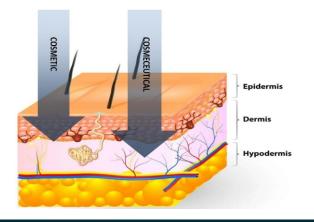


Fig (4): dermal penetration of cosmetics and cosmeceuticals



Fig(5): Most common skin conditions claimed by cosmeceuticals to be cured.

BENEFITS OF COSMECEUTICALS

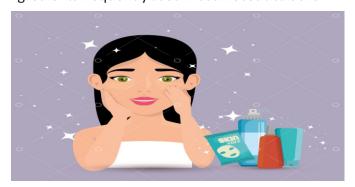
The number of key ingredients is more in cosmeceuticals. Hence, Cosmeceuticals are more expensive as they contain active ingredients in higher concentrations. Cosmeceuticals utilize complex ingredients developed recipes and frequently they contain novel ingredients. Cosmeceuticals are sold in clinical workplaces by skin health management experts who tailor a routine and request of use explicitly for you. The ingredients are applied in light of the fact that a few ingredients influence skin entrance – making different ingredients pretty much successful. Cosmeceuticals are used to treat skin conditions like hyperpigmentation, cellulitis, massive pores and acne. The tremendous majority of cosmeceutical products are for anti-aging, wrinkles, loss of elasticity and tone, and sunburn related conditions.Cosmeceuticals can work in tandem with topical prescription medications. If you are presently the usage of a prescription medication, cosmeceuticals can enhance your average treatment. For example, ingredients containing ceramides can limit dryness brought on by way of topical prescription tretinoin.





RISKS ASSOCIATED WITH COSMECEUTICALS

Skin can become irritated because cosmeceutical products might also include penetration enhancer and exfoliating substances like alpha-hydroxy acids or retinol. Cosmeceutical elements are generally unstudied in academia so most of these components come from lookup achievement of the cosmeceutical enterprise itself. Still, there is excellent proof that sure components do have some tangible advantages of the skin. Potential toxicity of some important chemical ingredients frequently used in cosmeceuticals are:



- 1,4-dioxane (C₄H₈O_{2,} diaxone) :Potent carcinogen eliciting cancer of breast, skin, and liver; potent inducer of irritation in the nasal cavity and tumors in the liver of animals, and endocrine disruption properties of 1,4-dioxane in animals
- Formaldehyde and paraformaldehyde: Proallergenicity, carcinogenicity, mutagenicity, and highlevel exposure correlates to an increased risk of developing myeloid leukemia.
- Parabens: ill-effects of parabens on male reproductive health (damage to spermatozoa), genotoxic effects of paraben on peripheral human lymphocytes. Benzalkonium chloride, imidazolidinyl urea, and diazolidinyl urea, trace metals, phthalates, isothiazolinone derivatives, phenoxyethanol and many more also have toxic effect. The list of such additives with potential or established toxicity profile is enormous. Hence, the toxicity of the cosmeceuticals should never be ruled out.



Fig (6) : Parabens

GLOBAL COSMECEUTICAL MARKET & TRENDS



According to Euro monitor International, the 2015 global retail sales of natural products-based cosmeceuticals were US\$2.98 billion, with this segment showing a 4% compound annual growth rate (CAGR). According to the study conducted by Indian Cosmetic Sector Analysis, the cosmetic market is around INR 356 billion. The Indian beauty and cosmetic market have been showing a consistent growth between 15 to 20% per annum.

The increasing need for the beauty products which are not injurious substances or ingestible drugs are been making a way to improve the market for cosmeceuticals are enduring to do so. The longing to look ever youthful and wonderful is fuelling the market development.





Disclosure and accessibility of active pharmaceutical ingredients in the coming future is additionally expected to help the market of cosmeceuticals. Additionally, with increase in disposable income and beauty conscious culture the market is expected to infiltrate further in India and China.



ADVERTISING OR FALSE ADVERTISING?



Companies are effectively utilizing internet and social platforms to reach out the maximum.

Association and consolidations are a typical standard as numerous restorative organizations have attached agreements with drug organizations for their turn of events and examination. Advertising must be truthful and non-deceptive and advertisers must have evidence to back up their claims.

An ad is deceptive if it contains a statement or omits information that is likely to mislead consumers acting reasonably under the circumstances.

According to the Federal Trade Commission Act and the FTC's Unfairness Policy Statement, an ad or business practice is unfair if:

- It causes or is likely to cause substantial consumer injury which a consumer could not reasonably avoid; and
- It is not outweighed by the benefit to consumers.

Some examples of withdrawn advertisements are listed below

- In 2009, an Olay ad for its "Definity eye cream" showed former model Twiggy looking wrinklefree — and a whole lot younger than her then-60 years. The British advertising regulator ASA banned the ad, after Liberal Democrat lawmaker Jo Swinson gathered more than 700 complaints against it. The digitally-altered spots were deemed to give a "misleading impression of the effect the product could achieve."
- In 2014, cosmetics company L'Oréal was forced to admit that its Lancôme Génifique and L'Oréal Paris Youth Code skincare products were not "clinically proven" to "boost genes" and give "visibly younger skin in just seven days," as stated in its advertising. According to the FTC, the claims were "false and unsubstantiated."In the settlement, L'Oréal USA was banned from making claims about anti-aging, without "competent and reliable scientific evidence substantiating such claims," the FTC said.





Fig (7): Withdrawn advertisements

October-December 2021



LIST OF COMMON COSMECEUTICAL INGREDIENTS AND THEIR PROPERTIES

Sl.no	Ingredient	Claimed action	Sources	Marketed Preparation
1	Allatonin	Skin Smoothening	Comfrey plant	Soft cleansing emulsion
2	Aloe vera	Softens skin	aloe vera	Lotus herbal moisturizers
3	Alpha. hydroy acids(AHA)	Exfoliates and improves circulation	Fruit acids (glycolic acid, lactic acid, citric acid, tartaric acid, pyruvic acid, maleic acid, etc)	Garnier anti- wrinkle preparation
4	Beta- Carotene	Minimizes lipid peroxidation and cellularantioxidant	Carrots and tomatoes	Environ body cream
5	Lupeol	Antioxidant and skin conditioning treatment	Cractacva nurvula	Sea tonic stretch mark removing cream
6	Oleanolic extract	Antioxidant, antifungal, improves texture and integrity of skin	Olive leaf	Trioxil an acne cream
7	Panthenol	Builds moisture and soothes irritation	Provitamin B5(broccoli, calf's liver turnip greens)	Penaten baby cream

CONCLUSION

The major threat of the use of any cosmeceutical product is, the product does not stay up to its claims. A well made cosmeceutical can assist enhance the tone, texture and brightness of skin but nonetheless they are not simply topical skincare products so sensibility is required in purchase and application. They may not absolutely eliminate skin conditions but can significantly enhance beauty and functionality of the skin.

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GLYCOLIPID BIOSURFACTANTS IN COSMECEUTICALS

Harshitha Gond Dhruv K

IV B Pharm





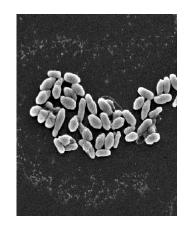
OVERVIEW

urfactants are amphiphilic compounds that contain hydrophobic and hydrophilic moieties which reduce surface tension and facilitate the formation of emulsions between liquids of different polarities. Surfactants show detergency, wetting, emulsifying, solubilizing, dispersing, and foaming effects when incorporated into cosmetics. Synthetically derived surfactants affect the environment and humans when used in the long run. Naturally derived surfactants are biodegradable, less toxic, and have higher ecological acceptability. The above-mentioned properties of naturally derived surfactants promise cosmetic safety and hence are in high demand. Biosurfactants are surfactants that are produced by microorganisms and have received wide attention regarding their biodegradability, low toxicity, ecological acceptability, and availability from renewable sources. These compounds are biosynthesized mainly as secondary metabolites and play critical roles in the growth or localization of their microorganisms They exhibit potential surface properties for cosmetic application. The major and most widely used biosurfactants in cosmetics and personal care products are glycolipids because of their physicochemical properties, biological activities, biocompatibility, and biodegradability.

Sophorolipids, rhamnolipids, and mannosylerythritol lipids are the most widely used glycolipids biosurfactants in cosmetics. Literature and patents relevant to these three glycolipids reviewed were emphasizing on the cosmetic applications including personal care products presenting the cosmetic efficiency, efficacy, and economic benefits of glycolipids biosurfactant.

HLB (Hydrophilic-Lipophilic Balance) measures the efficiency of the lipophilic portion of a surfactant molecule relative to its hydrophilic portion. This scale of 0 to 20 indicates the size and strength of the polar portion of the molecule compared to its non-polar portion. Although originally applied to non-ionic surfactants, its use has now been extended to ionic surfactants whose values are much higher, up to 50, based on the ionization properties. The higher the surfactant HLB value, the more hydrophilic it is, and the lower the value, the more lipophilicitis.

INTRODUCTION TO SOPHOROLIPIDS.



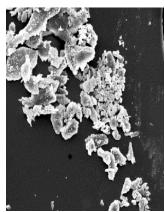


Figure 1: Photograph of 12 Day culture of Candida bombicola (a) and Biosurfactant (b) by SEM





Sophorolipids are glycolipid biosurfactant that is generally composed of carbohydrate heads and lipid tails. They belong to the class of non-ionic surfactants. Sophorolipids are synthesized in high concentrations by non-pathogenic yeasts which makes them attractive for further commercial production and use. They offer a vastly improved environment compatibility as compared to traditional surfactants, combined with excellent functional properties. Sophorolipids are the second generation glycolipids, a class that is obtained from renewable resources through biotechnological means. They possess good surface-active properties and show excellent skin compatibility, a property that is very important for cosmetic and personal care applications. Due to their emulsifying, antimicrobial, and other beneficial properties, they can be used in various other sectors.

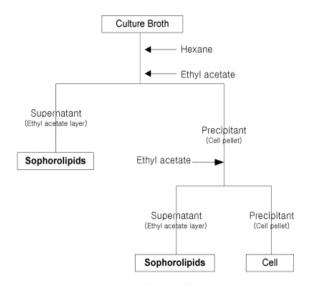


Fig. 1. Schematic diagram of sophorolipid preparation.

APPLICATION OF SOPHOROLIPIDS:

Cosmetics: Sophorolipids have a wide variety of functions and are used as emulsifiers, foaming agents, solubilizers, wetting agents, and detergents and have biological activities which are employed as active ingredients in cosmetics.

Sophorolipids have been shown to have good skin compatibility and excellent moisturizing properties. They are potent bactericidal agents and are used in the treatment of acne, dandruff, and body odors. They are thought to trigger several beneficial events related to the protection of hair and skin. They stimulate dermal fibroblast metabolism and collagen neosynthesis. They eliminated the surface portion of the protective layer of the epidermis as part of the wound healing process. They act as desquamating and depigmenting agents. They also possibly reduce subcutaneous fat overload by stimulating leptin synthesis in adipocytes and are suited for cellulite treatment.

Pharmaceuticals and therapeutics:

Sophorolipids have claimed to have antihuman immunodeficiency virus and sperm-immobilization activities. They can trigger cell differentiation instead of cell proliferation and the inhibition of protein kinase C activity of the human promyelocytic leukemia cell line HI60.

Miscellaneous: Sophorolipids are useful in secondary oil recovery, in removing hydrocarbons from drill material, and in the regeneration of hydrocarbons from dregs and muds. Saraya, a Japanese company has commercialized "Sophoron", a dishwasher containing sophorolipids as the cleaning agent. Sophorolipids possess antimicrobial properties and hence can be applied in the germicidal mixtures suitable for cleaning fruits and vegetables.

RHAMNOLIPIDS







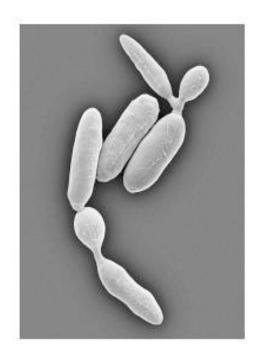
APPLICATION OF RHAMNOLIPIDS

1. Cosmetics: Rhamnolipid as an active ingredient is found to be effective for several skin treatments i.e., wound healing with reduced fibrosis, cure of burn shock, treatment of wrinkles hence are in demand in the health and beauty industry.

Detergents and cleaners: Rhamnolipids are natural emulsifiers and surface-active agents leading to their widespread usage in detergent compositions, laundry products, shampoos, and soaps.

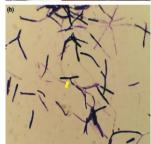
2. Pharmaceuticals and therapeutics: Rhamnolipids show low toxicity, surface-active properties, antimicrobial, anticancer, immunomodulation properties thereby showing promising applications in pharmaceuticals and therapeutics.

MANNOSLYERYTHRITOL LIPIDS









APPLICATION OF MANNOSLYERYTHRITOL LIPIDS

1.Cosmetics: Mannosylerythritol lipids were recently shown to be one of the most promising biosurfactants used in cosmetics because of their excellent surface activity. They can be used for the moisturization of dry skin and repair of damaged hair. It causes activation of fibroblast and papilla cells thereby causing skin appendage morphogenesis. They were demonstrated to show 1,1-diphenyl-2-picryl hydrazine radical-scavenging and superoxide anion scavenging activities in a concentration-dependent manner, thereby exhibiting antioxidant properties as well.

2. Pharmaceuticals and therapeutics:

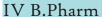
Mannosylerythritol lipids also exhibit versatile biochemical actions including antitumor and cell differentiation activities concerning human leukemia, rat pheochromocytoma, and mouse melanoma cells. In addition, they show a high binding affinity toward different immunoglobulins and lectins.





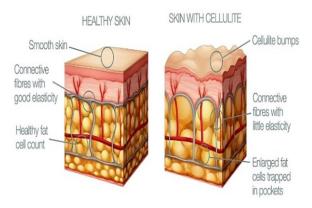
CELLULITE : A COSMETIC COMPLICATION

MD Nawab Ali Jahnavi Jaolekar





ellulite is skin alteration often described as an orange peel, mattress, or dimpling appearance on the thighs, buttocks and sometimes lower abdomen and upper parts of arms of otherwise healthy women. It is rarely observed in males, those men presenting with cellulite are mainly deficient in male hormones. Cellulite is cause by a build up a fat underneath the skin. Some women are more predisposed to it than other. The amount of cellulite depends on individual's genes, body fat percentage, and age. The thickness of your skin also affects the appearance of cellulite. Collagen fibers between the skin an muscles separate the underlying fat into multiple pockets. It can become more visible with age as the skin becomes thinner an loses elasticity. This exposes the rippled connective tissues underneath.



Causes:

- Hormones
- Poor diet
- Unhealthy lifestyle
- Accumulated toxins
- Genetics
- Weight gain
- Inactivity
- Pregnancy

Pathology:

There are three primary factors involved in the development of cellulite:

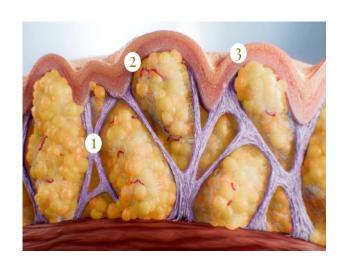
1. Fibrous septae

These collagen-rich bands tether the dermis to the underlying fascia and segment the fat layer into lobules.

2. Fat lobule protrusion

The fat lobules push up against the dermis; however, due to the septae tethering, they form mattress like protrusion on the surface of the skin.

3.Dermal thinning
Dermal thinning occurs proving less support to
contain the underlying soft tissues.









Treatment:

❖ Topical treatments

oMethylxanthines (e.g., caffeine) penetrate the skin to act directly on adipose cells, promoting lipolysis, Caffeine does break down triglycerides (fat) inside fat cells and induces them to release those triglycerides into the bloodstream. If fat is not oxidized (burned) for energy in muscles or other organs, it will inevitably be absorbed and stored by another fat cell.

Caffeine administered locally, such as in caffeinecontaining anti-cellulite lotions, is useful in lowering local fat because it helps release fat from fat cells in the specific region where it is applied, reducing local fat and cellulite.

Of course, if you don't exercise or eat a healthy diet while using a caffeine-based cellulite cream, the liberated fat will wind up in your bloodstream and be redeposited someplace else in your body. Indeed, part of it will be redeposited in the same location

Retinol

can prevent in vitro human preadipocyte differentiation. Lipid accumulation is suppressed and molecular markers of adipocyte differentiation such as adipocyte lipid-binding protein or stearoyl CoA desaturase mRNAs22 are down-regulated. The effects of RA on the adipose cells have however two particular features. First, addition of RA to cell cultures is only effective in blocking cell differentiation when performed at early stages of the process. Second, the analysis of marker genes, whose expression is characteristic of the differentiated phenotype of adipocytes, does not provide evidence of direct effects of RA (retinoic acid) on gene transcription through potential `negative RA responsive elements'. Retinoids work by prompting surface skin cells to turn over and die rapidly, making way for new cell growth underneath. They hamper the breakdown of collagen and thicken the deeper layer of the skin.







Physical and mechanical treatments

- o **Ultrasound**: High frequency vibrations provokes lipolysis, followed by lipoaspiration, and is used during liposculpture procedures. Ultrasound acts only on the subcutaneous tissue, with fair results regarding the localized fat.
- o **Thermotherapy**: This technique uses heat or cold to obtain vasodilation. Its effectiveness is questionable, as vasodilation itself may aggravate GLD, and the high temperatures may lead to protein denaturation.
- o **Pressotherapy**: This is a physiotherapy method which utilizes a pneumatic massager to perform sequential compression. This is done in the direction of the circulatory flow, activating the venous return, and is used to treat lymphatic, venous or mixed oedema of the limbs.
- o **Lymphatic drainage**: This is a massage technique, which consists of pumping movements using gentle and rhythmic pressures, which stimulate lymphatic flux. This reduces oedema. It must be performed in the direction of the lymphatic return.
- o **Electrolipophoresis:** This consists of the application of several pairs of thin (0.3 mm) long (5–15 cm) needles which are connected to a low frequency current generator. An electromagnetic field is created which modifies the interstitial tissue, aiding circulatory drainage and promoting metabolic changes and lipolysis.

Parenteral treatment:

FDA approved collagenase clostridium histolyticumaaes (Qwo^{TM}), biologic injectable treatment for cellulite. By injecting directly into cellulite, it may help to break down or release the collagen rich bands that pull on the skin surface and contribute to "dimpling" **QWO** initiates a process called enzymatic subcision and remodeling, which include three steps:

Enzymatic subcision_QWO treats cellulite by enzymatically subcising the fibrous septae.

_Fat lobule Reorganization: After subcision of fibrous septae, the fat lobules begin to recognize and spread more evenly. The tension at the subdermal junction is released, allowing for fat lobules to be reorganized Collagen creation & dermal thickening.

The enzymatic breakdown of the collagenous fibrous septae stimulates a wound healing-like reaction that results in the creation of new collagen, which helps thicken the dermis and rebuilds the collagen network. Over time, the fibrous septae may reform with new collagen, but will be thinner and smaller.



Conclusion:

Cellulite are normal, it is a condition in which skin appears to have lumps/dimples due to underline fat. It affects 90% of post adolescent women. There are currently hundreds of devices and medication that purport to treat cellulite. Most of the evidence supporting their efficacy is anecdotal, subjective or non-existent. There are many opportunities for further investigation, including non-invasive forms of treatment

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DOES A PREGNANT MOTHER FEEL INCOMPLETE WITHOUT MAKE UP?

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pregnant mother takes conscious efforts to look good which makes them feel good in the happy phase of pregnancy, which keeps them cheerful and positive but they should be having a basic idea and awareness about beauty products that should be avoided in gestation time which can harm both mother and developing embryo. Pregnancy hormones not only show up funny cravings like eating chocolates, pickles, fast foods, etc. these hormones also impact on facial glamor gradually but a pregnant mother should never be obsessed with this, it is a very common episode during pregnancy and lactation so one should not decide to misuse the cosmetics . Mood swing is very common occurrence in gestation this is because of hormonal shifts, where estrogen and progesterone are the culprits for the cause. These hormones will be not only affecting psychologically, But also shows changes on skin, most of the pregnant women will be dealing with pimples(acne) and also pregnancy hormones push skin cell production into overdrive, this will cause small skin polyps which usually occur over neck or under arms these are called as skin tags. In some case pregnancy hormones will induce brown facial splotches this occur on the

forehead, cheeks, and chin sometimes sunlight exacerbate the condition.



So pregnant mother should keep minimum exposure to sunlight, considering this pregnant mother might find alternative way by using sunscreen to over come this splotches progression, it is ok to use sunscreens but they should look after the brands which should be free from toxins for gestation and sunscreen SPF should be least 15 or above also the formulation. of the particular cream should be free from Vitamin A.

Yes, vitamins are essential during pregnancy but not all the essential/existing vitamins, a pregnant mother should be aware of vitamin A which is hazardous to the developing foetus. Vitamin A which is chemically called **retinol**, retinol is known to be a molecule that improves the skin texture, dyspigmentation, dryness, and fine lines. If you pick 9 out of 10 skincare cosmetics its formulation table shows up retinol in it.





Vitamin A is added to many cosmetic products, such as moisturizers, sunscreen, vitamin infused oils and antiaging creams. Vitamin A causes teratogenicity (foetus abnormality), vitamin A crosses placenta barrier when it is applied over the skin it gives its dermatological effect (protection and antiaging) but some are trapped between the skin and there are absorbed into the bloodstream, this can possibly cross placenta and causes fetal abnormalities. Vitamin A is a fat soluble, so our body stores excess amount in the liver. This accumulation of retinol which can have toxic effect on the body and lead to liver damage it can even cause birth defects also miscarriage in third trimester of pregnancy .The use of vitamin A in excess of the recommended dietary allowance (RDA) may cause fetal harm when administered to a pregnant woman; therefore, vitamin A in excess of the RDA is contraindicated in women who are or may become pregnant

Literature studies

In a prospective study of 22,755 women, high intake of vitamin A (retinol greater than 15,000 International units/day from combined sources of food and supplements or greater than 10,000 International Units/day from supplements) was associated with an increased incidence of birth defects. Incidences of malformations of tissues derived from neural crest cells (ie, craniofacial, CNS, thymus, and heart) that were only noted when high vitamin A intake occurred between 2 weeks preconception and 6 weeks post-conception demonstrated the greatest increase. The increase was less pronounced for musculoskeletal and urogenital defects. After correcting for confounding variables (ie, age, education, race, family history of birth defects, and folate, ethanol, or anticonvulsant use), the differences persisted. The study findings that vitamin A is potentially teratogenic were confined to vitamin A in the form of retinol. The study did not examine teratogenicity of vitamin A in the form of beta carotene.

A physician cannot consult a pregnant mother to cut off vitamin rich food like carrot, dairy products and also pregnant mother cannot calculate amount of vitamin a ingested/consumed unlike calories so she can control accumulation of vitamin A by avoiding cosmetics where retinol is used in it. At last considering all above studies and references we can conclude that pregnant mother should avoid use of vitamin A as much as possible to have safe and successful delivery, By avoiding creams and oral dosage forms that show up retinol in there formulation.

 One to be known that even applying nail polish in pregnancy has a bad impact on it . women's usually paint their nails to look pretty and to have attractive but not all nail paints in market is safe/good as we think especially to pregnant mother's

How nailpaints will impact for unsafe pregnancy?

Nail polish hinder baby's growth due to ingestion of chemicals used in it, the chances of ingestion of these chemicals is high in our Indian culture, in India most of use hands to eat meals unlike in other cultures so chances of ingestion of these chemicals is more. Almost all nail paints brands use chemicals such as formaldehyde, toluene, and dibutyl phthalate. At what extent these will be interfering we will be seeing below

• **TOLUENE** — it is a volatile liquid which gets evaporated at normal room temperature, so by inhaling during application is habitual however it will be causing irritation of throat, lungs, and eyes also exposure of this for long time will affect nervous system of the developing embryo, It can also cause headaches, dizziness, confusion, a faster pulse, nausea, vomiting, effects on the blood .Commonly toluene is used in nailpolish, it provides the smooth texture over nails so almost all brands in the market add it to most of the preparations to give good finishing to nail paints after application .





- FORMALDEHYDE- formaldehyde causes irritation of nose, eyes and throat if inhaled during application and it is not much harmful comparing to toluene, mother's body has tendency to breakdown formaldehyde, so it has low risk. Formaldehyde is used to enhance hardness which is required in the preparation of nail paints
- DBP (dibutyl phthalate) DBP may cause hormone-production problems in a fetus, reproductive issues, headaches, itchy eyes and more.

How to apply nail paints in pregnancy to avoid unsafe practices?

- Should choose a brand which is free from above toxins and should stick to same brand.
- o Always prefer acetone free nail polish removers
- Wash and remove the nail paints after the occasion don't leave it until paint deteriorate fully
- Always take help of others for applying paints, to avoid any accidental spillage or difficulty in application
- Sit in a good ventilation and always wash hands after handling those chemicals
- Preferably use one coat of nail polish than multilayer.

Using nail paints is not contraindicated in pregnancy until and unless all above safety measures are followed in a way it as to be.



Applying of lipstick is not a good practice during pregnancy, ingestion of its chemicals while eating and drinking is common and it is not safe, it is very harmful to mother as well as baby .If a pregnant mother applies lipstick regularly and frequency of application is also more resulting in increased rate of ingestion proportionally risk rate increases.

Lipsticks majorly contains lead which is hazardous during pregnancy, high levels can cause miscarriage and still birth also other pregnancy problems such as low birth weight or poor growth and premature delivery.



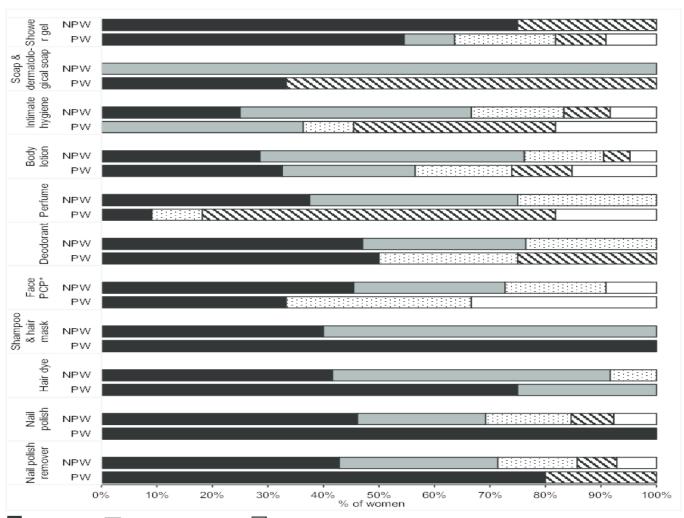
How to overcome this?

Organic cosmetics is trending nowadays so one can shift to organics which are made up of natural ingredients like beeswax, shea butter, sesame oil, almond oi, rose oil, honey, coca butter. These has good characteristics which lasts for long and healthy for lip care than chemical and colours, none of the above causes any threat to either mother or baby's health

- Always choose a lipstick which has less or free from lead
- Always look for a safety certification than concerning about price tag.



Criteria of choice of cosmetics during pregnancy



Ingredients Professional advice Brand

☑ Odour ☐ Other (price, habit, appearance and friends' advice)

Conclusion

Keeping cosmetics at arm's length during pregnancy will aid for the safe fetus development and as well as safe delivery this will out-turn to a good health for both mother and baby .One cannot convince to completely stop usage of any cosmetics, it is all of pregnant mother's attitude towards having a better and safe pregnancy, her priority should always be on ripening embryo inside her than concerning about her beauty and glamor, the grip of having same attitude is not only on pregnant mother it equally appeals to the care-taker of a pregnant mother during this particular period.

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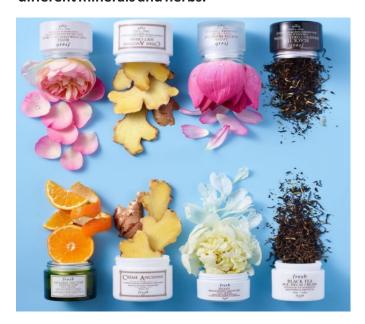
COSMECEUTICALS AND IT'S ROLE IN ECONOMY OF INDIA

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ancient days. People were using a variety of cosmetic products like Kajal, Surma, Bindi, Sindoor, Kumkum, Mehandi, Altaa and Alaras both for curative purpose as well as for beauty. Indian merchants used to trade herbal products to adjacent countries and afar. The ancient cosmetics were primarily extracts from the plant sources like turmeric (haldi), sandalwood, nuts and yellow and red clay of few regions, ashes (bhasmas) of different minerals and herbs.



COSMECEUTICALS AND ITS IMPACT IN INDIA

1. Rise in demand for natural and herbal products

Indian consumers are more inclined towards natural and herbal cosmetic products. The herbal cosmetics industry is expected to grow at a rate of 12% in India. The Indian cosmetics industry has numerous herbal cosmetic brands like Forest Essentials, Biotique, Himalaya Herbals, Blossom Kochhar, VLCC, Dabur, Lotus, Jovees, Kama Ayurveda, Patanjali, Just Herbs and many more.

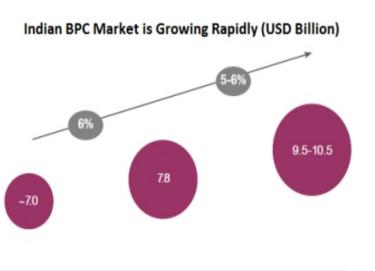
According to a recent research by Euromonitor, words such as 'natural', 'organic', 'botanical', 'free from' some harsh chemical, and even 'religious compliance', are the major factors behind the purchase of personal care products. The report says that over half of Indian consumers reported 'natural or organic' features influencing hair and skin care purchase decisions. While 71% of consumers surveyed said that they would pick up a face cream or lotion if it claimed to be 'natural', 38% said they would buy a shampoo or hair oil if it was made with 'botanical' ingredients. Even 'religious compliance' has swayed 17% consumers. Even foreign brands have now dived into natural products. French cosmetics brand L'Oreal has come out with Ayurvedic shampoo, conditioner, oil, and cream under its Garnier Ultra Blends brand, Hindustan Unilever re-launched Ayush and acquired hair oil brand Indulekha while Emami bought out Kesh King Hair oil. Patanjali Ayurved, in a short span, has become a household name. Patanjali has a vast collection of shampoos, soaps, and beauty products.

2014

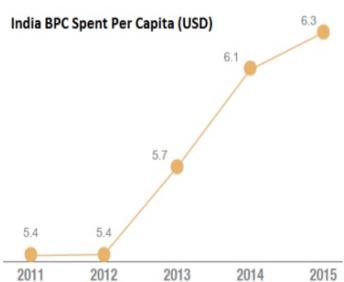
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2. Size and Growth Trends in the Domestic Industry



2016



Indian BPC Market Size (%) by Category

2021



Category	Growth '14-'16	Sub-category and growth		Evolution	
Hand care	16%			Newly emerging category consisting of nail, cuticle care and moisturizing creams	
Color Cosmetics	12%			Shift in usage of color cosmetics - from only special occasions to everyday use	
		Fairness	7%		
	9%	Male shaving	9%	Consumore moving towards	
Face care		Cleansing	15%	Consumers moving towards integration of health & wellness and	
race care		Lip care	20%	skin care products	
		Foundation	20%		
		Other creams	9%		
Hair care	5%	Oil	5%	Consumers are warming up to more evolved, western style hair care regimes	
		Shampoo	5%		
		Conditioner	10%		
Body care	4%	Toilet Soaps	2%	Non-traditional product categories such as Derma, body wash, sunscreen are growing	
		Deodorants	3%		
		Creams/Lotions	8%		
		Derma	32%		
		Sunscreen	9%		
		Body wash	9%		



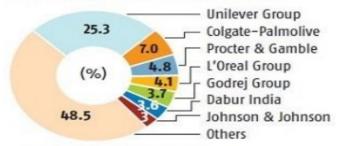


The Indian cosmetics and beauty products segment has been witnessing steady growth of late. It is primarily categorized into five major categories - body care, face care, hair car, hand care and color cosmetics. Indian beauty and personal care (BPC) industry is estimated to be worth USD 8 billion. India's per capita spend on beauty and personal care is it is growing in line with India's GDP growth. Many international brands like Revlon (the first international cosmetics brand to enter India in the mid-nineties), Avon, Burberrys, Calvin Klein, Christian Dior, Estee Lauder, L'Oreal, Max factor, Max Mara, Body Shop, Maybelline New York, MAC, Bobbi Brown and many more have been present in India for an extensive period of time.

The top three players in the Indian market are international players, namely **Hindustan Unilever**, **Colgate-Palmolive India and L'Oréal India**. The other prominent international players with a strong presence in the Indian market include Gillette India, Johnson & Johnson (India), Reckitt Benckiser (India) and Procter & Gamble Home Products.

Domestic players were catching up over the review period with the emergence of the trends towards natural, herbal and Ayurvedic products. Prominent domestic players include Godrej Consumer Products, Dabur India, Marico, Wipro Consumer Care & Lighting, Emami and Patanjali Ayurved.

Who dominate the Indian market (retail value share) market share in 2016



Source: Euromonitor, Economic Times

3. Factors for Growth

The emergence of electronic media and entertainment industry in a big way has not only enhanced the demand for cosmetic products within the country but also enlarged the user base among all strata of economy class. The economic liberalization accompanied with the reduction in excise and custom duties has encouraged the industry to improve its quality standard by adopting modernization with the infusion of imported plant and machineries. This sector which was witnessing around five per cent annual growth till 1993 is now witnessing around 25 per cent annual growth. A part of this, credit should also go to the sudden emergence of Indian beauties in the world scenario which had also attracted the youth towards the more use of these cosmetics.

The consumption pattern of cosmetics among teenagers went up substantially because of increasing awareness and due to the desire to look good. Over 68% of young adults feel that using grooming products boost their confidence.







About 62% of young consumers in big cities prefer to buy online beauty and grooming products whereas 45% of consumers tend to buy cosmetics and apparels from any shop of their convenience rather than a single shop. Both quality and value for money is being sought by consumers. Also, there has been a rising aspiration among Indian men to look better groomed, which has led to the Indian men's grooming market witnessing a growth of more than 42% in the last five years. This growth is faster than the growth rate of the total personal care and beauty industry in India. Interestingly, men who fall in the age group of 18 to 25, spend more money on grooming and personal care products than women in India.

4. Indian Economy

I India's retail beauty and cosmetics industry, currently estimated at \$950 million, is likely to almost treble to \$2.68 billion in the near future. Annual growth in the Indian beauty and cosmetics markets is estimated to remain in the range of 15-20 percent in the coming years, twice as fast as that of the US and European markets. The small scale cosmetic industry is currently providing a direct employment to the extent of over two lakh people while creating indirect employment avenues for another four lakh people in the country.

I India's cosmetics market is reportedly growing at 15-20 percent annually, twice as fast as that of the US and European markets. Demand for skin whitening

Over the last few years, cosmetics products have seen a growth of 60 percent. The number of salons has also gone up. Its growth rate is 35 percent. Cosmetic treatments are also growing at the rate of 5 percent.

products by men as well as women, is driving the

trend but other beauty products are not far behind.

The hair and beauty industry is seeing a per capita annual spend of \$1.2 which is expected to grow to \$6.2 in the near future. The spa and body treatment segment is estimated to grow approximately \$772 million over the next five to eight years. Driven by growing consumption in rural and semi-urban areas, the fast-moving consumer goods (FMCG) market is set to double from \$14.7 billion to \$30 billion in order to become the fourth largest sector in the economy with a market size in excess of \$14.7 billion.



CONCLUSION

India: A land of opportunities

The swift growth of the beauty business has not only impacted Indian firms to encourage competition in the space, but has also lured numerous international brands to the country. To give an instance, today, India has very few professional make-up lines that can cater to the wide range of salons and professional make-up artists across the country. This gives an opportunity to international professional make-up lines to penetrate into the market.





Similarly, the skincare segment in the Indian market is flooded with natural ingredients based products at present. Demands are high for products that are formulated using key ingredients like seaweed extracts and sea salts and other mineral-rich elements. Since these ingredients being exotic are found majorly in premium skincare segment, international players can seek to occupy a large share of the total space in the premium mass segment in the future. The key factors to successfully enter the beauty and cosmetics market in India include careful understanding and adaptation of Indian skin types and tones and customize products accordingly. During the initial years of entering the market, the volumes of sales are likely to be low while the cost of operations is observed to be high. Gradually the scenario will change as sales are expected to increase.



The application of cosmetics varies from person to person and from region to region on account of climatic and environmental factors and the products are made accordingly to suit the people of that region. With centuries of experience of extracting the best from natural dyestuff, flowers, roots, oils etc, India today manufactures a wide range of quality cosmetic production which have gained acceptance of consumers all over the world. Indian herbal cosmetics currently are being exported to countries primarily in Middle East and South East Asia.

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BEAUTY OF TAMANU OIL

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Due to its calming and relieving pain effects, the oil is used in massage for rheumatism and sciatica soothing, and highly appreciated for wound healing and analgesic properties. It's an evergreen pantropical tree distributed in Africa, Asia, and Pacific countries.

osmetopoeia refers to popular uses of plants for traditional cosmetics and body care that have always existed in many countries and cultures over the world, but this concept is very poorly documented as written reports. Even Tamanu oil is one among them.

Tamanu oil is known as 'THE MIRACLE OIL'.

It is an excellent example of traditional remedy which has come to broader attention due to a combination of effective use in traditional setting and scientific research collaborating its benefits. Tamanu oil is pressed from nuts of either Calophyllum inophyllum or Calophyllum tacamahaca (ati), tropical trees belonging to the calophyllaceae family. The nuts yield 70–75% the greenish-yellow inedible oil. It is also called as Beauty leaf oil, Kamani oil, Honne oil, Alexandrian laurel oil, Punnaga oil and sometimes referred as "Green gold". Tamanu oil is amazingly effective for the treatment of everything from acne and acne scars, general scars, stretch marks, diabetic sores, psoriasis, sunburn, blisters, burns, cuts, eczema, herpes sore, insect bites and the reduction or complete removal of unsightly age spots.



Tamanu oil as an active cosmetic ingredient recorded as "Calophyllum inophyllum seed oil" by the INCI (International Nomenclature of Cosmetic Ingredients). Therefore, this oil is known to be included in regenerating and protective cosmetic formulas such as skin restorative, sunburn protection, soothing, and wrinkle or stretch mark prevention. The active constituents of Tamanu oil were identified as coumarin derivatives — calophyllolide, the molecule of which contains a lactone and methoxy group and — calophyllic acid, which results from the saponification of the calophyllolide.





Other components of tamanu oil are (i) free fatty acids, glycerides, and sterols, (ii) terpenoids and steroids (canophyllal, canophyllol, canophyllic acid) and (iii) coumarinic derivatives: calophyllolids (natural neo-flavonoids with antibacterial, anti-inflammatory and blood anti-coagulation properties), inophyllolids (natural neo-flavonoids with antiviral properties), calophyllic acid (natural neo-flavonoid with antimolluscidal and healing activities)



SKIN - HEALTH BENEFITS

Over the years, people have discovered that tamanu oil products have several beauty and health benefits for healthier and beautiful skin to healthy hair.

In 2007, Said et al. explored the anti-UV activity of tamanu oil for eye protection. They found that the botanical oil displayed a significant capacity to absorb UV radiation, even at low concentrations (1/10,000, v/v), with a sun protection factor ranging from 18 to 22. Concentrations of C. inophyllum oil of up to 1% were not cytotoxic to human conjunctival epithelial cells, with the agent acting against oxidative stress and DNA damage. Considering the apparent antioxidant and cytoprotective effects of C. inophyllum oil in the study, the researchers concluded that the oil has potential as a natural UV filter in ophthalmic formulations.

Antimicrobial activity: Calophyllum inophyllum has acidic phenolic groups which could be attributed to the presence of tannins. Tannins are soluble in water and the presence of alkaloid gives a bitter taste. Glycosides have been known to lower blood pressure, although some workers have attributed the cardiac action of these oils to the presence of the alkaloids. The presence of phenolic compounds gave acidic properties and could possibly be responsible for the antimicrobial activities.

Helps with acne: Unlike other comedogenic oils (coconut oil), tamanu oil will not clog pores. And it has some acne-fighting properties and also has some antibacterial activity aganist Propionibacterium acnes, the bacteria associated with acne, so it is a safe moisturizing oil to use on acne skin.

Antioxidant and anti-UV properties: The xanthones and coumarins in tamanu oil are powerful antioxidant compounds that helps to reduce the production of reactive oxygen species in the skin cells. Additionally, it is also one of the few oils that may absorb the harmful UV

Antifungal activity: The ethanolic, chloroform and aqueous extracts of *Calophyllum inophyllum* Linn examined against different fungal cultures exerted significant growth inhibition against two species of genus *Trichophyton simile* and *Trichophyton mentagrophytes*. It acts against human pathogens like *Aspergillus niger* and *Candida albicans*. The isolated compounds friedelin, canophyllol, ionophynone from these extracts have shown the antifungal activity.

Moisturizing property: Tamanu oil has a higher fatty acid content than many other oils, making it especially beneficial for addressing dry skin. More specifically, it contains both oleic and linoleic fatty acids, which may give it powerful moisturizing





Scar reduction: One promising study by A. C. Dweck and T. Meadows has shown that test subjects with aged scars had reported measurable improvement in scar appearance after using tamanu for nine consecutive weeks. The improvement was noticeable from week six onwards. Considering the scale of the study, however, more research needs to be done for this property of tamanu oil to be considered beyond that of traditional wisdom.

For Wrinkles: The skin-regenerating properties of the tamanu oil can be used to treat and prevent the appearance of skin wrinkles. Obviously, some wrinkles will arrive with age and there is no stopping that, but it is possible to stave them off for longer, using the oil's nourishing and skinfriendly agents. This oil contains different fatty acids which help new skin tissue to regenerate.

Oil-Cleansing property: Cleans the pores without stripping the skin of essential moisture. Unlike traditional face wash formulas that foam or lather and often contain artificial fragrances and other irritants, botanical oils are all-natural and much gentler. They're even recommended for oily and acne-prone skin because the healthy oils bond with and dissolve dirty oils that cause blemishes.

Because tamanu oil is comedogenic, it's best to mix it with a lighter oil like jojoba when using it as a cleanser. One part of tamanu to three parts of jojoba is an ideal ratio. Add a splash of frankincense essential oil for extra blemish and redness-fighting power.

Spot treat blemishes: Tamanu oil contains antimicrobial properties that helps to remove blemishes. With a potency sometimes compared to tea tree oil, it should be used only in small amounts. Even though tamanu oil can be directly applied to skin, it's best to dilute it first with an

equal amount of carrier oil (say, sweet almond or sunflower) to avoid irritation, especially when using to treat sensitive and aggravated skin.

Soothe chapped lips: Tamanu oil is a remarkable remedy for dry skin and a natural treatment for parched lips. The Miracle oil is not only helpful for skin health but also works a as a magic for hair benefits. The fact that it can be used on chemical burns makes it a welcome addition to African -American and Latina hair care or for others who chemically or heat-straighten their hair. Tamanu oil's ability to regenerate and act as an antiinflammatory and antibiotic make it a welcome addition to the curly hair care, particularly in protective and healing formulas for those who use heat or chemical formulas on their hair looks. Many of us with kinky, curly, and wavy hair seek natural ingredients to help with hair growth or to stop breakage — in this area Tamanu oil shows promising results. Not only this oil is recommended for skin disorders or scalp burns, but its regenerative properties make it the oil to reach for when trying to recover from hair loss. It is a wonderful aid for people who are seeking relief from brand-new, super tight cornrows or microbraid extensions, which often produce a burning, itching, irritating sensation on the scalp or even freshly twisted locks as well as on Nubian Knots.

TAMANU OIL BENEFITS FOR HAIR

Promotes Hair Growth

Tamanu oil is good for hair growth because of its powerful nutrient content. Tamanu oil is rich in nutrients like linoleic, oleic, palmitic, and stearic acids that deeply nourish the hair follicles and contribute to faster hair growth.

Fights Scalp Fungal Infections

Tamanu oil is amazing when it comes to fighting off fungal infections.







So, if people suffering from scalp inflammation, which is characterized by a painful, itchy, and red scalp. Some conditions like scalp eczema and scalp psoriasis also greatly benefit from tamanu oil's anti-inflammatory properties.

COSMECEUTICAL PRODUCTS CONTAINING TAMANU OIL

1. Kamree Skincare 50gm Tamanu Balm



2. Under Eye Cream



3. Qurez Tamanu, Pumpkin and Frankincense



4.Tamanu & Tea Tree - Oily Skin Cream (40gm)



5. Juicy Chemistry Organic Face Cleanser for Normal to Combination Skin



6. Neroli, Rosehip and Tamanu Body Butter







7. SILK PROTEIN SHAMPOO BAR+ TAMANU CONDITIONER BAR FOR BOUNCE & SHINE



Conclusion

"Cosmetopoeia concept" will launch discussions about renewing interests of "plants of the past" for "future valuations" namely as bio sourcing ingredient for cosmeceuticals and will inspire innovative ways for sustainable development of different countries and cultures over the world. Tamanu oil is an ethnocosmetic product.



Tamanu oil as an active cosmetic ingredient recorded as "Calophyllum inophyllum seed oil" by the INCI (International Nomenclature of Cosmetic Ingredients). Due to its properties and benefits, tamanu oil is included in different cosmetic formulation as an active ingredient such as for skin regeneration, after sun protection, soothing and irritation, calming, wrinkle and stretch mark prevention. Indeed, traditional uses of tamanu oil was good source of inspiration for its cosmetic modern uses and new ways of valuation

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BIG BOON IN THE COSMECEUTICAL INDUSTRY

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anotechnology is a highly useful tool for the design of innovative solutions for many sciences including health and beauty. The understanding and handling of compounds at nanoscale have allowed the development of materials with interesting characteristics to use in cosmetic science as seen in the design of nanoparticles of different materials as carrier systems for cosmetic actives. New carriers of cosmetic ingredients in the form of nanoparticles are currently the focus of research centres all over the world. With the purpose of increasing physicochemical stability of both incorporated actives and the system itself, solid lipid nanoparticles (SLN) and nanostructured lipid carriers (NLC) have been developed. NLC are the second generation SLN composed of solid lipid matrix incorporated within liquid lipids. NLC are superior productive alternative to the existing systems for delivery of topical, cosmetic and pharmaceutical actives

Skin care products contain active ingredients that are either hydrophilic or hydrophobic, each category has its limitations when used in topical formulations.





To overcome these limitations, many factors should be considered, such as the skin area in the human body, the duration of application, the mechanism of action, and the potential side effects. For example, hydrophilic agents cannot penetrate the stratum corneum due to their polarity, while hydrophobic agents have an unpleasant oily texture for patients. The use of transdermal delivery systems (TDDS) is an alternative technique that facilitates the penetration of active ingredients through the skin. Like other topical formulations, these systems offer non-invasive drug delivery compared to parenteral routes, but have limitations due to the low permeability of drugs through the skin barrier. Therefore, the development of a robust TDDS is required to improve drug delivery.





Prolonged and controlled release of active ingredients/bioactive from SLN

Enhanced permeation through skin, improved skin hydration, safe, biocompatible and highly stable system

> High loading capacity of NLC for active ingredients/bioactive

SLN and NLC based cosmetics

Advantages of solid lipid nanoparticles (SLN) and nanostructured lipid carrier (NLC) based cosmetic products.

Lipid carriers include liposomes, oil-in-water (o/w) emulsions, multiple (w/o/w) emulsions and microemulsions. Apart from these systems, solid lipid nanoparticles (SLN) and nanostructured lipid carriers (NLC) have been developed with a rationale to protect and improve the stability of actives and the system itself.

SOLID LIPID NANOPARTICLES

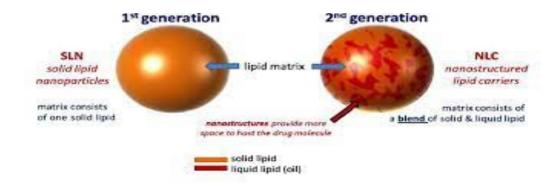
Solid lipid nanoparticles (SLN) have been introduced as a novel drug delivery system for pharmaceutical drugs in various application routes. They also represent a promising carrier system for cosmetic active ingredients due to their numerous advantages over existing conventional formulations.

Compared to liposomes and emulsions, solid particles possess some advantages, e.g. protection of incorporated active compounds against chemical degradation and more flexibility in modulating the release of the compound. Advantages of liposomes and emulsions are that they are composed of well,

tolerated excipients and they can easily be produced on a large scale, the pre-requisite for a carrier to be introduced to the market. The SLN were realised by simply exchanging the liquid lipid (oil) of the emulsions by a solid lipid, which means lipids being solid at room temperature but also at body temperature SLN possess some features which make them promising carriers for cosmetic applications:

- (1) The protection of labile compounds against chemical degradation has been shown, e.g., for retinol and tocopherol.
- (2) Depending on the produced SLN-type, controlled release of the active ingredients is possible. SLN with a drug-enriched shell show burst release characteristics whereas SLN with a drug-enriched core lead to sustained release.
- (3) SLN act as occlusives, i.e. they can be used in order to increase the water content of the skin.
- (4) SLN show a UV-blocking potential, i.e., they act as physical sunscreens on their own and can be combined with molecular sunscreens in order to achieve improved photoprotection..





NANO STRUCTURED LIPID CARRIERS

Nanostructured Lipid Carriers are the second generation SLN composed of solid lipid matrix incorporated within liquid lipids. The diameter of NLC ranges between 10-1000 nm. The solid lipid matrix immobilizes the drug and prevents the particles from coalescing with one another, while the liquid oil droplet within the solid matrix increases the drug loading capacity of the particles. Liquid lipids are better solubilizers of drugs than the solid lipids. NLC are composed of physiological and biodegradable lipids exhibiting low systemic toxicity and low cytotoxicity. The small size of the lipid particles ensures close contact to the stratum corneum and aid in permeation of the drug through the skin. Due to the solid lipid matrix, a controlled release from these carriers is possible. These were developed around 1999 by R.H. Muller to overcome some potential limitations of the solid lipid nanoparticles (SLN) as below,

- Pay-load for number of drugs is too low
- Drug expulsion during storage
- High water content of SLN dispersion

NLC as smarter generation of lipid nanoparticles are promising candidates to provide skin targeting along with occlusive effect and prolonged release

NLC exhibit a biphasic drug release pattern that is, initial burst release of drug followed by a sustained release at a constant rate. The liquid lipid located in the outer layers of the nanoparticle's forms drugenriched casing which leads to burst release of the drug at the initial stage

Long term stability of incorporated drug during storage

NLC are easily stabilized with a minimum possible concentration of surfactants along with best results of stability, entrapment, and release

Skin health benefits of SLN and NLC

The film formation properties of SLNs can be attributed to their small size and vast specific surface area, thus making adhesive properties which finally lead to the high penetration of compounds into the skin layers. In spite of various reported investigations regarding the advantages of incorporating active cosmetic and pharmaceutical ingredients into SLNs, there are few reports on the occlusion effects of SLNs and their benefits for therapeutic application

The demand of natural skin care products is steadily growing since consumers perceive them as safe. Currently, cosmetic manufacturers are focusing their efforts on developing innovative natural products to address skin-aging signs, thus meeting consumers' needs of healthy appearance and wellbeing.







To prevent or treat skin aging, topical supplementation with antioxidant is regarded as one of the most promising strategies. However, most antioxidants presently used in skin care formulations show unfavourable physicochemical properties such as excessive lipophilicity or hydrophilicity, chemical instability and poor skin penetration that actively limit their effectiveness after topical application. Therefore, Solid lipid nanoparticles have been widely investigated as delivery systems for antioxidants to improve their beneficial effects in the treatment of skin aging.

Enhancement of chemical stability of actives -SLN and NLC belong to the most frequently employed carriers for the delivery of cosmetic actives. However, they are not, or only to a limited extent, able to protect chemically labile actives against degradation

SLN have a spherical like shape and so have excellent lubrication action. SLN are also sufficiently viscous so they are easily applies and sufficiently elastic so they adhere and selfimmobilize onto the skin.

Applications of Lipid carriers in cosmeceuticals

- **Antiaging**
- **Sun screens**
- Anti-acne
- Skin lightening
- Moisturizer etc.,

Marketed finished cosmetic products

1. NanoRepair Q 10 Cream and Serum

The first two world-wide finished products with NLC, NanoRepair Q 10 Cream and NanoRepair Q 10 Serum, were introduced to the market by the German company Dr. Rimpler GmbH. Market introduction took place at the cosmetic fair "Beauty" in Munich October 2005





2. NanoVital

NanoVital is the third product launched by Dr. Rimpler GmbH in June 2006. NanoVital contains Q 10 in a concentration of 0.1%, optimised for the use as day cream. In addition, it contains a moderate concentration of a UV blocker (nanosized titanium dioxide) to minimise the photo-aging of the skin.

3. NLC products in the cosmetic line "IOPE"

NLC containing black currant seed oil are the basis for three new cosmetic products of the premium line IOPE by the South Korean company Amore Pacific: SuperVital cream, eye-cream and serum









4. Allure skin cream



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Ideally preferred properties for cosmetic proucts

































COSMECEUTICAL REGULATIONS

Tejeswini

IV B Pharm



osmeceuticals represent a new category of products placed between cosmetics and pharmaceuticals that are intended for the enhancement of both the health and beauty of skin. Encompassing an ever-increasing part of the skin care industry, cosmeceuticals are formulated from a multitude of ingredients, the main categories of which are discussed in this article. Given the growing interest in these products among patients and the strong claims made by manufacturers, it is important that physicians recognize these agents and understand their benefits, limitations, and potential adverse effects.

Cosmetic goods are regulated by various regulatory bodies around the globe and all have their own rules and regulations. Cosmetics has altered definitions based on region or country and its similar terms can see in global market like Cosmeceuticals and OTC products, depending on specific type of product being produced, manufacturers may elect to conduct additional testing to ensure the safety and usefulness of their cosmetic products. Cosmetic manufacturers may also perform additional tests to meet specific quality or performance requirements of buyers and consumers

Regulators in different countries defined cosmetics in different ways.

India: As per Drugs and Cosmetics Act 1940

Cosmetics Act 1940 and Rules 1945, Cosmetic means any article intended to be rubbed, poured, sprinkled sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

United States: Defines cosmetics as "articles intended to be rubbed, poured, 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, and articles intended for use as a component of any such articles; except that such term shall not include soap".

Cosmetic regulatory requirements in certain countries:

Although regulations applicable to cosmetic products are increasingly being harmonized to reduce international barriers to trade, there are still important differences to take into account when marketing or selling cosmetics in major markets around the world. The following sections discuss mandatory and specific regulatory requirements in certain countries such as US, Europe, Australia, India.





A) US cosmetics regulations:

The cosmetic and personal care products industry supports a strong and vigilant FDA. FDA monitors the safety of cosmetic products that are being marketed by number of ways such as Voluntary Cosmetic Registration Program, Inspections (to manufacturing facilities), Surveys of products (periodically buys cosmetics and analyzes), Cosmetic Ingredient Review (CIR) expert panel and Reports from consumers and health care providers.

Cosmetic products are regulated by the FDA through different laws like:

Federal Food Drugs and Cosmetic Act (FD&C 1938)" and "Fair Packaging and Labeling Act".

FDA has categorized the cosmetics as mentioned:Hair Products, Makeup, Nail Care Products, "Organic" Cosmetics, Soaps & Lotions, Tattoos & Permanent Makeup on the other hand the VCRP (Voluntary Cosmetic Registration Program) database as well provides important information on these cosmetics.

Cosmetic Regulation - FD&C Act:FDA has authority to inspect firms, equipment, unfinished and finished materials, containers with labeling and has listed information about Adulterated/Misbranded ingredients:-Adulterated:Injurious to users under conditions of customary use because it contains, or its container is composed of, a potentially harmful substance, chemical contaminant or prohibited ingredient Prohibited Cosmetic Ingredients: Hexachlorophene, Mercury Compounds, Chlorofluorocarbon Propellants, Acetyl ethyl tetramethyl tetralin (AETT), 6-MC, Dioxane&Certain cattle materials, Restricted Cosmetic Ingredients:(permissible as unintentional contaminants):Bithionol, Halogenated Salicylanilides, Chloroform, Vinyl chloride, Zirconium containing complexes in aerosol cosmetic products, Methylene chloride Labeling: The cosmetics distributed in the US must comply with the systematic Cosmetic labelling guide published by the FDA under the authority of the FD&C Act. Labeling means all labels and other written, printed or graphic matter on or accompanying a product

The main requirements are:

- a) Principal Display Panel (PDP):
- Identity statement: The common/usual name, descriptive name, fancifull name, illustration prominence, statement.
- **Net quantity:** Quantity of contents, in terms of weight, measure, numerical count.
- Warning: If the cosmetic product contains an ingredient for which adequate substantiation of safety has not been obtained, a warning must be placed on the PDP like "Warning - the safety of this product has not been determined"
 - b) Information Panel:
- Name and place of Business: Principal place of business, corporate name, Manufactured for xyz, distributed by xyz and complete Address.
- Language: The complete labelling contents required by regulation must be in English. If the label contains any foreign language representation, all statements required local language.
 - Distributor statement
- Ingredients name & listing: Applicant may use INCI name or in absence, but applicant should use the name given by the US Pharmacopeia, NF, Food chemical Codex and USP dictionary of drugs names.Ingredients must be listed on product labels in descending order by quantity. Exemptions are made for active drug ingredients, ingredients with less than 1% concentration and color additives which can appear in disorder because of small amounts.



Cosmetic Warning Statements: As per FD&C Act, Cosmetics may be hazardous to consumers must be bear appropriate label warnings. e.g.: Flammable cosmetics such as aerosols, cosmetic manufacturers market cosmetic products that do not contain ethyl alcohol as "alcohol free".

Material facts: Applicant should reveal material facts (e.g.: directions for safe use), or applicant's product will be considered as misbranded or adulterated.

Cosmetic Claims: Information on cosmetic labeling, including claims, must be truthful and not misleading. In addition, if a product is marketed with claims for purposes such as treating or preventing disease, or affecting the structure or function of the body, it's a drug according to the law and it must meet the requirements for drugs, even if it affects the appearance because FDA does not have the authority to approve claims before cosmetics go on the market.

Penalties: The law provides severe penalties for products that do not meet these standards. Specifically, the law gives FDA the authority.

➤ Cosmetic products and ingredients are not subject to pre-market review and approval. Instead, manufacturers are responsible for substantiating the safety of their products and ingredients, and for providing consumers with complete and accurate information regarding a product's ingredients. The sole exception to this approach involves the use of color additives, which are subject to separate FDA requirements. To enforce its regulations, the FDA collects samples of cosmetic products for examination and analysis through routine inspections of manufacturing facilities, as well as of imported products.

➤ USFDA states that a product can be both drug and cosmetic, the classification of products are arranged & simple and depending upon the product claim.

B) Indian Cosmetics Regulations:

Cosmetics products in India are regulated under the Drugs and cosmetics Act 1940 and Rules 1945 and Labeling Declarations by Bureau of Indian Standards (BIS)

The procedure to be followed in order to manufacture cosmetics in India, BIS sets the standards for cosmetics for the products listed under Schedule 'S' of the D&C Rules 1945. And Schedule M-II classifies cosmetics into 11 broad product categories.

Dossier submission: Product information technical file need to provide with all documents and evidences as per authorities approved & described product category and subtypes requirements to the authority.

Application for Grant or Renewal of a manufacturing license: State Drug authorities of Respective States are responsible to issue manufacturing Licenses. The application has to be submitted in Form 31 along with a license fee of 3500 INR with an inspection fee along with required information like:

•List of Equipment, Manufacturing Facility details with minimum area of 15 Sq. Meters,

■Technical Competent personnel details, Relevant SOPs are required for obtaining manufacturing permissions. The specifications should comply the BIS/International Standards.

■The manufacturer has to ensure that the production is done in the presence of a competent and qualified technical staff. Before granting or refusing the license, the Licensing Authority is required to order inspection of the whole premises. The appointed inspectors submit a detailed report to the Licensing Authoritywhich can then decide whether to grant the license or not. Licensing Authority would grant FORM 32, which is License to manufacture cosmetics for sale or for distribution with No. of license and date of issue.

Imported cosmetics registration in India:

In Indian market there are so many imported brands are selling/marketing, which have good quality & efficacy as per claim but in terms of safety few cosmetics are very dangerous and harmful for human health as per their own countries testing procedures or regulations and due to lack of strict guidelines or regulations in India they are marketing





Products to controlling that there is a Checklist for Pre Screening of Applications for Grant of Registration Certificate in Form 43 under the provisions of Drugs & Cosmetics Rules and authorized by CDSCO, Dossier mustsubmit to authority as perthe requirements for imported cosmetics registration before commercialization in India:-e.g.: Covering letter by the applicant, Form-42, Treasury Challan, POA, Schedule D III, Original copy of Label, FSC/MAletter and Mfg. License, Product spec.& testing protocol, List of countries where Market Authorization or import permission or registration was granted, Pack insert, Soft copies of the information about the brands, products andmanufacturer.

Legal metrology: This is Packaged Commodity Rules, 2011 having laws and procedures for packaging, labelling, import and tax laws in India. The legal metrology officers have assess the declaratory compliances of the manufacturer, importer and packer, performed in the interest of the end consumers but as per survey/study, it has stringent and complex compliances& not much in favor of Industries/Importers.

Shelf-life data: BIS says that, Manufacturer has to conduct suitable shelf life study as per protocols which ensure product integrity throughout the intended shelf-life period through appropriate data. Visible signs of degradation such as fermentation, rancidity, change in colour, and such other tests as applicable to the product shall be used to prove the stability of the product.

Labelling requirements of cosmetics: D&C Rules, 1945 says, labelling requirements must be full fill such as Product name along with site addresson both the inner and the outer labels. If the container is small in size then the principal place of manufacturing and the pin code are enough.

The outer label should clearly specify the net contents of the ingredients used in the manufacture of the product. The inner label should contain the 'directions for use' along with any warning or caution that may be necessary.

Safety data: BIS says that, Proof of safety data/such studies should be available with the Manufacturer/distributer need to be produced, if

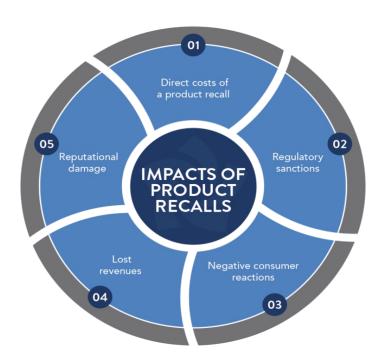
inform the consumer, if there are any precautions to required. Manufacturer/distributershall suitably be taken while using the products, which are known to show safety concerns in specific individual/population on the labels of such products.

PRODUCT RECALL:

Recall is an action taken to withdraw/remove the drugs from distribution or use including corrective action for which deficiencies are reported in quality, efficacy or safety. The defective products related to quality includes Not of Standard Quality, Adulterated or Spurious drugs. Safety and efficacy related recalls include serious adverse reactions and death. Recalls also include drugs prohibited under the Provisions of Drugs & Cosmetics Act and also those products for which product licenses are suspended/cancelled.

PRODUCT RECALL IN INDIA:

In the Drugs & Cosmetics Act & Rules, there are references for product recalls, complaint and adverse reactions in Para 27 & 28 of Schedule M and also conditions of license for defective product recall in Rule 74(j) and Rule 78(i), but effective and uniform recall procedure, with time lines at every level of supply chain is required and at present auditing and accountability is not in place.





1.Recall Classification: Recall classification is a numerical designation, I, II, or III, that is assigned to a particular product recall that indicates the relative degree of health hazard by country regulatory authorities.

Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death and as well as banned under 26A of Drugs and Cosmetics Act 1940.

Class II is situation in which the use of, or exposure to, a defective product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

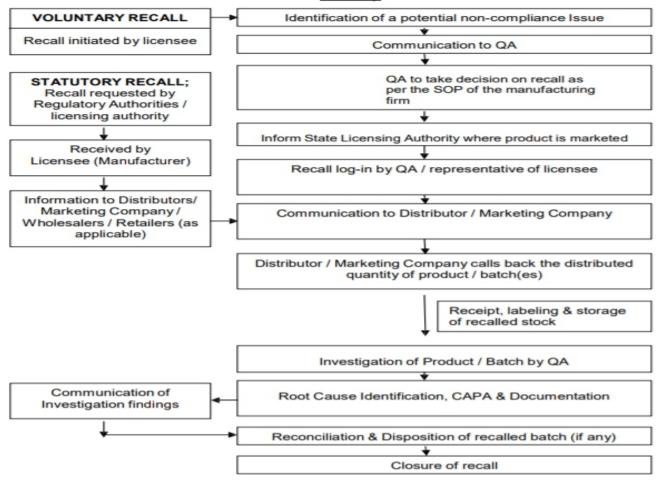
Class III is a situation in which the use of, or exposure to, a defective product is not likely to cause any adverse health consequences.

- **2.TYPES OF RECALL:** Any batch of a product not meeting the defined quality standards has to be recalled from the market. Recall can be of two types;
- **a.Voluntary Recall:** Voluntary recall can be triggered by any incident that affects the quality, safety and efficacy of the batch/product in question such as
- 1. If the batch or batches are found to be not complying with the regulatory specifications during the post marketing stability study
- 2. If the batch is found to be defective during investigation of market complaint. 3. During any failure investigation, if it is observed that the failure under investigation might have adverse quality impact on already released batch (e.g. possibility of contamination, mix-up, degradation etc).
- 3. During any failure investigation, if it is observed that the failure under investigation might have adverse quality impact on already released batch (e.g. possibility of contamination, degradation etc).

- 4. If any unusual observation is noted during visual inspection of retention samples which indicate an impact on quality of the product after investigation.
- 5. If the post marketing surveillance reports /pharmacovigilance reports indicates that there is serious safety risk associated with the product.
- **b.Statutory Recall:** Statutory recall can be triggered in response to the direction or mandate by the Drug Regulatory Authorities (Central/State) in one or more of the situations as follows:
- 1. To recall the drug product/batch, considered to be in violation of the laws, administers such as not of it standard quality etc.
- 2. To recall the banned drugs.
- 3. Labeling and / or Promotional materials, that are considered to be in violation of law.
- 4. Product, violation Rule 106 (Diseases under Schedule J).
- c. Levels of Recall: The level (or depth) of recall of a product/batch shall be determined based on recall classification and level to which distribution has taken place. There are three levels of recall such as;
- Consumer or user level
- Retail level
- Wholesale level
- **4.Time Lines for Effective Recall System & Rapid Alert:** Based on the category of risks involved,



Overview of Process Flow Rapid Alert & Recall System: Activity



a time line of within 24 hours up to a maximum of 72 hours for Class I recall, for class II recall up to a maximum of 10 days and for Class III recall up to a maximum of 30 days is allowed. The time line for initiation of recall procedure to commence from the receipt of information as notified by the concerned State/ Central Drugs Control Department under statutory recall or voluntary recall by the manufacturer on its own. The recall has to be initiated immediately without any prejudice of the outcome of Section 25(3) and Section 25(4) of the Drugs & Cosmetics Act 1940 for adducing the evidence. The time line for stopping sale/distribution of defective product under Class I shall be ensured within 24 hours and the physical recall being completed within 72 hours. The Class II and Class III recalls shall be ensured upto 10 and upto 30 days respectively.

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LIVING WITH COVID-19!

Darshan K R

IV Pharm D



ife has been on roller coaster since 2-3 years now, covid has changed life of millions of people around the globe. It has not been easy and struggle for the recovery is still an on-going process and in recent times the threat of new variant is a major concern.

The World Health Organization (WHO), reported on the meeting of the Technical Advisory Group on SARS-CoV-2 Virus Evolution (TAG-VE), which is an independent group of experts that periodically monitors and evaluates the evolution of SARS-CoV-2 and tries to determine if specific mutations and combinations of mutations alter how the virus behaves. A recent meeting was on SARS-CoV-2 variant: B.1.1.529, called Omicron, which was first reported to the WHO from South Africa on November 24.



"This variant has a large number of mutations, some of which are concerning," the WHO notes. "Preliminary evidence suggests an increased risk of reinfection with this variant, as compared to other [variants of concern]. The number of cases of this variant appears to be increasing in almost all provinces in South Africa."

The agency advises that current SARS-CoV-2 PCR diagnostics are able to detect the variant. Because in one widely used PCR test one of the three target genes is not detected—S gene dropout or S gene target failure—the test therefore can be used as a marker for the Omicron variant, pending sequencing confirmation. "Using this approach, this variant has been detected at faster rates than previous surges in infection, suggesting that this variant may have a growth advantage," the WHO notes

The approval of oral antiviral has brought some hopes for the future. On December 23, 2021, the FDA granted EUA to Merck for its oral antiviral drug

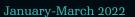
- Molnupiravir and to Pfizer for its oral antiviral drug Paxlovid, both authorized to treat COVID-19.Molnupiravir is authorized for the treatment of mild-to-moderate COVID-19 in adults aged 18 years and older who are at high risk for progressing to severe cases and for whom alternative treatment options are not accessible or clinically appropriate.
- Paxlovid (nirmatrelvir/PF-07321332 and ritonavir) is authorized for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients aged 12 years and older weighing at least 40 kg, with positive SARS-CoV-2 tests, who are at high risk for progressing to severe COVID-19, including hospitalization or death.

STAY SAFE, MASK UP AND GET VACCINATED













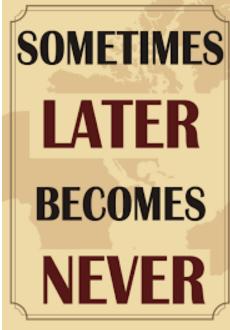


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