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Moisturizers Free of Paraben, Mineral Oil, Alcohol and Ingredients from Animal Origin (Pama) - A New Way Forward

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Abstract

Effective management of dry skin conditions involves the treatment of a defective skin barrier. Moisturizers enhance and preserve the smoothness of the skin in patients with dry skin conditions as well as those with healthy skin. Many ingredients of moisturizers have the potential to cause irritant and allergic contact dermatitis; therefore, it is necessary for clinicians to be aware of such potential allergens to manage and advise their patients' accordingly. Moisturizers free of paraben, mineral oil, alcohol and ingredients from animal origin (PAMA) have an advantage since they don't cause sensitivity, allergy or dermatitis. This review will help dermatologists understand the need and benefits of low allergen containing moisturizers.

Introduction

Inadequacy in barrier function is a prime factor in development of dry skin conditions [1]. According to a questionnaire based survey, 32.3% of Indians had sensitive skin that made them more likely to suffer from dry skin conditions [2]. Therefore, optimum water content in stratum corneum (SC) is of utmost importance in preserving skin's appearance and texture. In the acute phase of atopic dermatitis (AD), topical corticosteroids are frequently an important part of the therapy procedure. Systemic adverse effects, such as inhibition of the hypothalamus-pituitary-adrenal axis, are a serious issue with topical corticosteroids [3]. Moisturizers are common personal care products and widely prescribed by dermatologists for managing dry skin conditions. Cosmetics/skin care products consisting of paraben, mineral oil alcohol and ingredients from animal origin (PAMA) are few of the main culprits of causing irritant and allergic reactions.

Limitations of PAMA containing moisturizers

Parabens

Since parabens are rapidly absorbed and can build in the body, they are one of the most used preservatives. The most prevalent allergens are butyl paraben, methyl paraben, propyl paraben, and ethyl paraben, which were discovered in 61.6% of the moisturizers tested [4]. Contact dermatitis caused by parabens results in rash, pimples, dry, and scaly skin. Furthermore, parabens have been linked to the development of persistent dermatitis, which raises the likelihood of sensitivity to topical therapeutic drugs. Literature suggests that parabens are endocrine disrupting chemicals (EDCs) that might cause fitness and functional problems.The presence of unmetabolized form of parabens in human breast cancer tissue has sparked controversy concerning its hazardous potential [5].

Alcohol

A study observed that 23.6% of moisturizers included benzyl alcohol, a common contact allergen [4]. Repetitive topical application and use of moisturizer has been documented to produce reactions [6]. Toxicological reactions observed are subjective irritation, contact urticarial, non-immunologic type, immunologic type, allergic contact dermatitis, and immediate-type reactions.

Mineral Oil

There has always been a controversy regarding mineral oil and its benefits. Petrolatum, and paraffin oil are the most commonly used mineral oil in topical cosmetic products. They have been a concern in regulatory areas of consumer products such as cosmetics and food [7]. Long-term use of mineral oil causes occupational folliculitis [8]. Medicinal white oils or waxes cause mild erythema on damaged skin. Moisturizers containing 10% mineral oil make the skin slightly more sensitive to UV [7]. As a result, the mainstay of prevention is avoiding contact with such chemicals.

Ingredients from animal origin

Contact allergies to animal-derived compounds such as lanolin and wool alcohols are becoming more common. Lanolin made from sheep`s wool was found in 9.8% of moisturizers, making it the ninth most common allergen, and reactions to lanolin more frequently occur on compromised skin, similar to paraben sensitivity [4].

The above data suggests that PAMA ingredients can potentially cause sensitivity, allergy and delayed hypersensitivity reaction. Contact dermatitis and chronic irritant dermatitis resulting in rash, pimples, and dry and scaly skin may develop. Patients with AD are at risk of flare-ups resulting in worsening of their clinical condition. PAMA ingredients are known to cause persistent dermatitis, increasing the risk of allergy and sensitivity to topical therapeutic drug ultimately leading to delayed clinical benefit. Thus moisturizers without PAMA ingredients maybe a more suitable option for patients with dry skin conditions including AD and psoriasis.

Need of Natural Moisturizing Agents

Moisturizers are common personal care products and widely prescribed by dermatologists for managing AD. Many of the

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ingredients mentioned above have the potential to cause irritant and allergic contact dermatitis (ICD and ACD). Hence, dermatologists must be aware of such allergens to avoid ACD and ICD and improve clinical outcome. Patients must be advised according to their skin sensitivity and history of known allergens. Moisturizers containing natural effective ingredients may be more suitable for improving skin hydration. Consequently, natural moisturizers may be used in moisturizing cosmetic formulations and also as a complement in the treatment of dry skin. Explained below are few natural PAMA free moisturizing ingredients.

Mango butter

Mango butter, also known as mango oil, is made from the seeds of mango trees. The oil content of dry seeds varies between 4 and 13% [9,10]. Mango butter is highly recognized for its bacteriostatic and anti-inflammatory properties, indicating that it could be used as a cosmetic ingredient for healing and protection [11]. Its saturated fatty acid profile is dominated by oleic (42%) stearic (40%) and palmitic (8%) acids, which account for up to 50% of the saturated fatty acid profile [12]. The unsaponifiable matter in mango butter, which is made up of tocopherols, phytosterols, and triterpenes, helps to minimize wrinkles and skin roughness, as well as its capacity to heal, protect, and rebuild the skin's lipid barrier. Mango butter is an effective formulation for sensitive skincare products because of all of these qualities. It is thought to be a viable alternative to cocoa butter and mineral-based emollients.

Aloe vera

Aloe vera is beneficial in variety of skin diseases like seborrheic dermatitis, psoriasis vulgaris, wound healing, and it has healing effect, anti-inflammatory action, moisturizing and anti-aging effect, anti-septic effect, anti-acne effect, laxative effect, antiviral action, anti tumor activity and effect on immune system [13]. Moisturizing effect is by increased production of collagen and elastin fibres making skin more elastic, soft, and less wrinkled. Moisturization in dry skin provides improved skin integrity, reduced fine lines and wrinkles and decreases erythema [13]. Aloe vera contains 75 potentially active constituents (Table 1).

Aloe vera freeze dried extract is an effective ingredient for improving skin hydration through humectant mechanism. It is used to retain skin moisture and integrity of skin which makes it a potent cosmetic formulation. As a complementary treatment aloe vera can improve wound healing, treat dry skin and improve health of society [14,15]. Aloe vera formulations with only 0.25% and 0.50% (w/w) extract is known to increase the water content of stratum corneum. Other formulation with (0.10%, 0.25% and 0.50%) extract is known to have same impact after 2 weeks of application [14]. In one study, participants were asked to discontinue all oral medications and replace topical applications with botanical anti-inflammatory moisturizer for a period of 2 weeks. The results showed significant improvement in irritation, erythema, desquamation, roughness, dryness, itching, and overall skin appearance [16]. Butters are intensive moisturizing cream that maintains hydration and overall integrity of the skin by improving skin barrier function, making it more resistant to external irritants. Aloe vera butter is a plant based butter that it provides hydration, softens and heals dry skin and has a good safety profile [17]. Evidence suggests thatafter two weeks application of 0.1, 0.25 and 0.5% of aloe vera extract, skin hydration is increased [18]. Most commonly used formulation for psoriasis is aloe vera extract (0.5%) in a hydrophilic cream [17,19].

Shea butter

Shea butter processed from the nut of *vitellaria paradoxa* (shea tree) contains antioxidants such as stearic acid, linoleic acid, catechins, and is used for inflammatory dermatoses such as psoriasis and atopic dermatitis [20]. Shea butter is composed of five major fatty acids, including palmitic, stearic, oleic, linoleic, and arachidic acids. It also contains triterpene acetate and cinnamate esters, demonstrating anti-inflammatory and anti-tumor promoting effects [21]. Clinical studies have demonstrated shea butter as skin aging treatment, which regenerates skin and gives smoother, clearer skin. Shea butter had cicatrizing action in 70% of cases of hand dermatitis, sun burn and scars. A cream with shea butter was also demonstrated to promote good moisturization of the skin compared to placebo [22]. in a pediatric study, the cream containing shea butter extract did not differ in acceptability or efficacy from a ceramide-precursor product for eczema [20].

Table 1: Active constituents present in aloe vera [13].

Active components	Benefit
Vitamins Vitamin A, C, E, B12, folic acid and choline	Vitamin A (Retinol) - antioxidant, anti-aging, humectant (at high concentration) Vitamin C (ascorbic acid) - antioxidant, increase collagen production Vitamin E (tocopherols and tocotrienols) - antioxidant
Minerals Calcium, chromium, copper, selenium, magnesium, manganese, potassium, sodium and zinc	Minerals are required for efficient functioning of enzymes.
Enzymes Alliase, alkaline phosphatase, amylase, bradykinase, carboxypeptidase, catalase, cellulase, lipase, and peroxidase]	Enzymes help in breakdown of sugars and fats
Sugars Monosaccharides (glucose and fructose) and polysaccharides (glucomannans/polymannose)	Improves skin regeneration by increasing collagen production
Anthraquinones aloin and emodin	Anthraquinones act as analgesics, antibacterial and antivirals
Fatty acids Cholesterol, campesterol, β-sisosterol and lupeol	Fatty acids have anti-inflammatory action along with antiseptic and analgesic properties
Hormones Auxins and gibberellins	Hormones help in wound healing.
Amino acids 20-22 human required, 7-8 essential	Helps in wound healing
Others Salicylic acid, lignin and saponins.	Saponin cleanses the skin and lignin enhances penetrative effect of other ingredients.

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Glycerin

Glycerin has been hypothesised to incorporate ceramides, which play an important role in improving the barrier function of dry flaky skin by easing digestion. The proportion of lipids in the solid form, such as eicosapentaenoic (EPA), docosahexaenoic (DHA), and stearidonic acid, may rise in dry skin, and glycerine may assist keep the lipids in a liquid crystalline state at low relative humidity [23]. In a randomized study, moisturizer with 20% glycerine appeared to be a suitable alternative to urea/sodium chloride in the treatment of atopic dry skin. Furthermore, adverse skin reactions such as smarting were felt significantly less among patients using the glycerine moisturizer compared with the urea/saline cream [24].

Vitamin E

After attempting numerous medications, such as antihistamines, steroids, and cyclosporine A, the majority of patients get discouraged. Vitamin E lowers the level of immunoglobulin E (IgE) antibodies in AD patients in recent research [3]. Tocopherols and tocotrienols are both types of vitamin E, however only alpha and gamma tocopherols are biologically active [25]. The most important lipid soluble antioxidant found in cell membranes is vitamin E. In the stable form of tocopheryl acetate, vitamin E prevents oxidation of chemical components found within the bottle of the moisturizer. This preservative function coupled with excellent skin conditioning effects is the main reason that vitamin E is frequently added to moisturizers [26].

A randomized, double-blind, placebo-controlled trial in patients with mild-to-moderate AD concluded that vitamin E 400 IU/day significantly improved itching, extent of lesion and severity scoring of atopic dermatitis (SCORAD) index ($p<0.05$) compared to control after four months of treatment. As vitamin E has no side effects with a dosage of 400 IU/day, it can be recommended for the treatment of AD [3]. A single-blind clinical study reported remarkable improvements in facial erythema, lichenification, and the appearance of normal skin in subjects with eczematous lesions who were given 268 mg of vitamin E and these effects were mostly due to the decrease in pruritus. In another randomized, double-blinded, placebo-controlled trial with 45 eczema patients, SCORAD assessment showed improvement in the patients who ingested vitamin E supplements [22]. In a recent Italian study, 46% of patients in the vitamin E group showed improvement compared to only 2% of patients in the placebo group [27]. A meta-analysis concluded that vitamin E improved the SCORAD Indexin eczema patients [28].

Human body cannot produce this vitamin and the skin levels of vitamin E depend on its oral or topical use. Alpha-tocopherol prevents oxidative stress of free radicals on cell membrane. Vitamin E protects the macrophage membrane against oxidative damage and reduces production of prostaglandins through affecting the immune system. Although contact dermatitis, burning, and itching have been reported on topical use of vitamin E, none of them occurred in patients receiving vitamin D (400 IU/day) [3].

Squalene

Squalene is an isoprenoid molecule, a component of human sebum that is one of the most prevalent lipids produced by human skin cells. It is a single oxygen quencher, protecting skin from lipid peroxidation due to ultraviolet and other ionizing radiation exposure. About 60% of dietary squalene is absorbed in humans. It is carried in serum in conjunction with very low-density lipoproteins and is found throughout the human body, with the highest concentration in the skin [29]. Squalane, a saturated form of squalene is less susceptible to oxidation. Thus, squalane is thus more commonly used as a moisturizer. Although the body produces squalane naturally, its synthesis drops dramatically around the age of thirty, contributing to dry skin. Squalane has the added benefit of not having an oily feel, being odourless, non-comedonal, antibacterial, and suitable for sensitive skin, despite the fact that it is technically oil [21].

Cocoa butter

Pertaining to skin health, cocoa components have been utilized in diseases, such as skin cancer, psoriasis, acne, and wound healing. Cocoa has great potential not only for the treatments of skin diseases, but also for their prevention [30].

The overall mechanisms and advantages of PAMA free moisturizing ingredients is depicted in Figures 1 and 2.

Burden of different dry skin conditions in India

Atopic dermatitis, contact dermatitis, dyshidrotic eczema, hand eczema, neurodermatitis, nummular eczema, and stasis dermatitis are the different types of eczema [31]. Dermatitis has a variable incidence in India, ranging from 0.24-0.42 % in children aged 0-14 years, according to an out-patient department (OPD) study [32]. Dermatitis affects 0.9% of children aged 6-7 years in India, according to a survey for adolescents and parents conducted by the International Study of Asthma and Allergies in Childhood (ISAAC) [33]. The reported prevalence of hand eczema in the general population is around 10% [34]. It is difficult to report the exact prevalence of hand eczema since it is underreported and very few seek medical attention [35]. Depending on age and geography, the prevalence of AD ranges from 11 to 21%. Furthermore, about 15-20% of children and 1-3% of adults have steroid sensitive dermatoses [36].

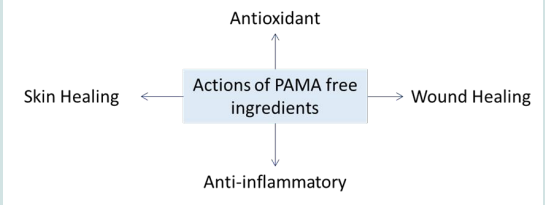

Figure 1: Mechanism of action of PAMA Free Moisturizing Ingredients.

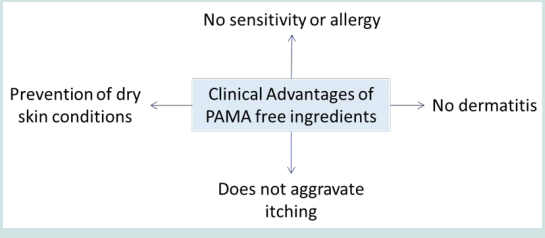

Figure 2: Advantages of PAMA Free Moisturizing Ingredients.

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Role of moisturizers in the management of atopic dermatitis

Moisturizers considerably reduce the severity of AD and symptoms of inflammation, such as pruritus, erythema, fissuring, and lichenification. Moisturizers also help to prevent flare-ups of AD. They also aid in the reduction of prescription medicine usage [37,38]. The different actions of moisturizers are mentioned in Figure 3. Moisturizers can be classified as occlusive, humectants and emollients (Figure 4).

Place of Moisturizers in the management of atopic dermatitis and psoriasis

Different guideline recommendations for using moisturizers in atopic dermatitis and psoriasis are mentioned in Table 2.

Moisturizers are the core of the management of AD. Evidence suggests that the use of moisturizers reduces and AD severity, along with decreasing the amount of prescription anti-inflammatory treatments required for disease control. Moisturizers are therefore a cornerstone of AD therapy and should be included in management plans [39]. For all patients, daily showers or baths followed application of emollients and moisturizers, with avoidance of trigger is the basic management and flare prevention [40]. Moisturizers and emollients should be used in the following cases: minimal psoriasis, napkin psoriasis, psoriasis of the folds, psoriatic skin damaged by previous local treatments, and in pregnancy or women of childbearing age [41]. According to the Indian consensus, varying skin types (oily, dry, combination, normal) guide the selection of amount, frequency and type of moisturizer. Therefore, an ideal moisturizer must be tailored with attributes adaptive to most circumstances and applicants [29].

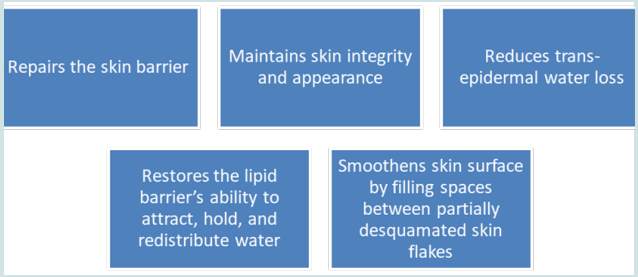

Figure 3: Different actions of Moisturisers [36].

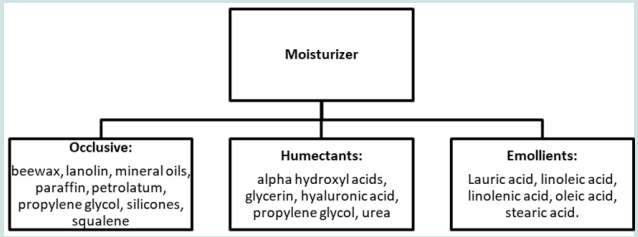

Figure 4: Classification of moisturizers [36].

Moisturizers for Covid-19

According to the data, 4.5% of Covid-19 patients presented with cutaneous manifestation such as itching, urticarial, vesiculopapular rash, acral erythema, maculopapular rash, irritant contact dermatitis, and others [42]. In India, an upsurge of hand dermatitis cases without any previous history has been observed amidst the pandemic [43]. Few cases of new onset ACD/ICD have been observed. Among all conditions, dryness due to hand hygiene tops the list followed by ACD & ICD (6.2% and 1.4%, respectively). Lipid barrier of skin is depleted due to the regular use of lipid dissolving alcohols and detergents, leading to xerosis and thereby ICD or ACD. Lower concentration of lipid dissolving alcohol and alkaline pH of causes the dehydrative effect [35]. Another reported problem was 'Acne and Skin breakdown', after 2-3 hours of wearing mask. Commonly affected areas included bridge of the nose and cheek bones, attributed to frequent changes and tight fitting masks and goggles.

Moisturizers, emollients, barrier creams and low potency topical steroids are recommended as symptomatic treatment, for reported conditions and to prevent skin breakdown [44,45]. Moisturization can be the sixth step in hand hygiene protocol. Regular applications of moisturizing hand creams can reverse glove induced maceration and minor erosions [34]. (Jindal R) Instructions of applying moisturizer each time immediately after hand wash, before glove occlusion and a thick layer every night has been provided by the American Academy of Dermatologists (AAD) [46]. American Contact Dermatitis Society recommends moisturizers for both prevention and treatment of xerosis and dermatitis due to hand hygiene [47]. Furthermore, the application of moisturizers seems to prolong the disease-free interval in patients with controlled hand eczema [24].

Table 2: Mentions different guideline recommendations for using moisturizers in atopic dermatitis and psoriasis.

Guideline	Recommendation
American Academy of Dermatology (AAD) [39]	Moisturizers are the main primary treatment for mild disease and should be part of the regimen for moderate and severe disease. Moisturizers are also an important component of maintenance treatment and prevention of flares
Expert consensus, India [36]	The regular use of moisturizer has short and long term steroid-sparing effects and reduces the frequency of acute episodes. Moisturizer should be used at least twice a day and should be more frequently used during acute flares.
Asian-Pacific region consensus guidelines [54]	• Regular moisturizer application for atopic dermatitis maintenance and adjunctive therapy. • Chronicity and severity of AD, along with patient age, treatment compliance, and economic background should all be taken into account when selecting an appropriate moisturizer for AD patients. • Other considerations include adjuvant properties of the product, cosmetic acceptability, and availability over the counter. • Well-defined clinical phenotypes of AD could optimally benefit from specific moisturizers.
The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) guidelines [55]	Use an emollient in conjunction with topical corticosteroids for 4 to 8 weeks to help reduce itching, desquamation, and prevent quick relapse of psoriasis when topical corticosteroids are discontinued. (Strength of recommendation: B; Level of evidence: II)

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Table 3: Study characteristics and results of using moisturizers in dry skin disorders.

Study design	N	Indication	Intervention and duration	Results	Ref
RC; MC; controlled, parallel-group	55	AD or chronic atopic disease	Canoderm cream 5% (coconut oil, emulsifying wax, hydrogenated canola oil, propylene glycol, carbomer, dimethicone, hard paraffin, glycerol polymetacrylate, propyl- and methyl parahydroxybenzoate, sodium lactate solution, lactic acid, glyceryl stearate, polyoxyethylene stearate, purified water) 26 week maintenance period	the relative risk of recurrence reduced by 53% in 22 moisturized patients, and the risk of relapse was reduced to around one-third of the risk of no treatment Median time to relapse for patients treated with moisturizer was more than 180 days (duration of the study) compared with 30 days for the no-treatment group. 68% of the patients treated with the moisturizer and 32% of the untreated patients remained free from eczema during the observation period.	[49]
RC; phase 3	173	infants under 12 months old treated for inflammatory lesions by moderate- and/ or high- potency topical corticosteroids	Emollient for 6 weeks	The amount of moderate- and high-potency corticosteroids used in 6 weeks decreased by 7.5% (not significant) and 42% ($p<0.05$), respectively, in the emollient group. The SCORAD index, and infants' and parents' quality of life significantly improved ($p<0.0001$) in both groups	[50]
Observational PRO study	400	psoriasis	Venusia max cream (shea butter, aloe butter, mango butter and cocoa butter along with propylene glycol, glycerine, glycol, emulsifying wax, cyclomethicone, dimethicone, cetyl alcohol, stearic acid, ethyl paraben, propyl paraben, disodium edetate, zinc oxide and fragrance) 4 weeks	significant reduction in both the mean DLQI score (66.7%; $p<0.001$) and mean DASI score (84.6%; $p<0.001$	[17]

AD - Atopic dermatitis; DASI - Dyshidrotic Eczema Area and Severity Index; DLQI - Dermatology life quality index; MC - Multicentre; PRO - Patient reported outcome; RC - Randomized controlled; SCORAD - Severity scoring of atopic dermatitis

Clinical Evidence of moisturizers for the treatment of dry skin disorders

A Cochrane review (2016) concluded that most moisturisers showed some beneficial effects; prolonging time to flare, reducing the number of flares and the amount of topical corticosteroids needed to achieve similar reductions in eczema severity [48]. Maintenance therapy with a barrier-improving moisturiser on corticosteroid-healed (betamethasone valerate) sites lowered the incidence of atopic dermatitis return in AD patients [49]. Emollient treatment for six weeks significantly reduced the high-potency topical corticosteroid consumption and improved quality of life in infants with AD [50]. Clinical efficacy of moisturizers is depicted in Table 3.

Lipid-rich moisturisers can successfully treat ICD based on clinical evidence [51]. Most moisturisers have positive effects, such as extending the time between flares, reducing the number of flares, and lowering the dose of topical corticosteroids required to achieve equivalent eczema severity decreases [52]. Literature suggests that moisturisers improve clinical symptoms,transepidermal water loss (TEWL) and stratum corneum hydration [53]. An intensive plant-based butter moisturizing cream (Venusia Max) significant improved quality of life by 67% and reduced eczema severity by 84.6% when used as an adjuvant treatment option for the management of psoriasis [17].

Conclusion

Moisturizers are common personal care products and widely prescribed by dermatologists for managing dry skin conditions. Skin care products consisting of allergens like paraben, mineral oil alcohol and ingredients from animal origin (PAMA) cause irritant and allergic reactions. Patients must be advised according to their skin sensitivity and history of known allergens. Natural moisturizers containing PAMA free ingredients may be more suitable for improving skin hydration. Consequently, natural moisturizers may be used in moisturizing cosmetic formulations and also as adjuvant therapy for the treatment of atopic dermatitis and other dry skin conditions.

Conflicts of interest: Dr. Monil Yogesh Neena Gala, Dr. Snehal Sameer, and Dr. Rahul Rathod are employees of Dr. Reddy`s Laboratories, India.

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