PORIM'S EFFICACY LABORATORY FOR COSMETICS AND TOILETRIES



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osmetics and toiletries cover a wide range of products and can be divided into 4 main categories, i.e. skin care, hair care, oral hygiene and colour cosmetics. The two most dynamic sectors are the skin care and hair care and much of the growth is seen in the Asia Pacific region (Shaw 1996, SPC ASIA Oct/ Nov 1996). Skin care product sales are expanding regionally, with the greatest growth expected to be in Malaysia, Thailand and Indonesia. All are forecast to grow by at least 10% annually (Weiss, 1995). The total skin care market in the three countries was about US\$550m in 1993, rising to US\$650m in 1994 and optimistically forecast to reach \$1bn by the year 2000. The hair care forecast for Malaysia, Thailand and Indonesia are 3.2%, 1.3% and 2.8%, respectively (SPC ASIA Dec.1996). India and China are expected to have the highest growth in both sectors.

With the tremendous potential for market growth in the Asia Pacific region, the intensification, of research and development in cosmetics and toiletries in Malaysia is very much desired. Furthermore with the trend to go for natural and environmentally friendly products, palm-based materials together with other natural plant extracts as active ingredients are obviously the best choice for development of cosmetics and toiletries. This can only be obtained through a proper research and development (R&D) in cosmetics and toiletries including efficacy tests.

Efficacy tests both *in vivo* and *in vitro* need to be carried out in order to be able to make any claim substantiation on the effectiveness of palm-based cosmetics or the specialty ingredients used in the cosmetic formulations. Efficacy test can be very costly. It is estimated that (in Italy) an *in - vivo* on human (20 subjects), costs about RM 60,000.00 per test.

Currently, there is no company within ASEAN that can carry out the efficacy test. Therefore, the establishment of Efficacy Laboratory in PORIM is a necessity, in order, to fully support R&D activities and to fully realize the marketing potential of palmbased cosmetic products developed. It is also a strategic necessity for the region to strengthen not only the R&D, but also to position Malaysian-made cosmetics and toiletries in the global market. Availability of the Efficacy Laboratory in PORIM will be able to support the Malaysian cosmetic industry, especially once the cosmetic legislation is enforced in Malaysia, as safety and efficacy data must be available for any claim substantiation before the products can be marketed locally, as well as globally.

CURRENT STATUS

The Cosmetics and Detergent (CND) Group in the Advanced Oleochemical Technology Centre (AOTC) of PORIM has acquired the knowledge and skills in formulation of cosmetic and toiletries products. Efforts have focused on maximizing the utilization of palmbased products and derivatives in the product formulation and also incorporation of minor components from palm oil products such as vitamins E & A, as functionality ingredients. In the skin care category, several products such as moisturizing cream and a lotion enriched with palm vitamin E, have been developed. The lotion and cream can be formulated using palmbased oleochemicals, such as glycerin, fatty acids (lauric, myristic, palmitic, stearic acids), fatty alcohols and their esters for various purposes, such as emollients, humectants, emulsifying agents and antioxidants. Since palm-based oleochemicals are plant derived, products formulated using them are natural and expected to be mild, environmentally friendly and acceptable to all religion.





The PALMIANIS range of hand and body creams and lotions developed by PORIM is formulated with almost 98% palm-based materials with the other 2% comprising preservatives and perfume. Various lotions and creams with different feels and characteristics can be formulated by varying the percentages of the raw materials used. For specific functions or nichness, other active ingredients can be included in the formulation, such as Vitamin E for anti-ageing, arbutin and kojic acid for whitening and sunscreen agents for sun protection.

Other products that have been developed are facial cleansing milk, shower gel, anti-ageing gel, skin whitening lotion (incorporating local active ingredient) and sunscreen products. In the colour cosmetic category, lipstick formulations incorporating polyglycerol esters have been developed. These demonstrate the varieties and versatility of palm-based derivatives.

AOTC's collaboration with HR Marketing Sdn. Bhd. has resulted in development of a whole range of personal care products from soap, lotion, cream, cleanser, toner, slimming gel, etc. incorporating goat's milk as the specialty ingredient. In particular, the goat's milk soap has reached the overseas markets of Brunei and Thailand.

In order to be able to carry out efficacy tests on the products, PORIM has taken another step forward in establishing the Efficacy Laboratory for Cosmetics and Toiletries in AOTC.

Efficacy Laboratory in PORIM (AOTC)

Efficacy Laboratory for Cosmetics and Toiletries has now been set up in PORIM (AOTC). The test facilities set up consist of *in - vivo* Innocuity (Safety) Evaluation, Efficacy Evaluations and Microbiology Tests. Tests available are as indicated. The cost of each test will be decided later and all requests can be directed to PORIM (AOTC), Lot 9 & 11, Jalan P/14, Seksyen 10, Bandar Baru Bangi, Selangor. Tel No:03-8255708 and Fax No: 03-8256197.

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Why?

We do we need to carry out safety, efficacy and microbiological evaluation? This is because cosmestic legislation requires a thorough assessment of product safety and the objective substantiation of all claims relating to product tolerance and efficacy. The cosmestic legislation in Malaysia is currently being studied by the 'Biro Pengawalan Farmaseutikal Kebangsaan, Kementerian Kesihatan'.

When?

It is important to carry out the safety/efficacy tests during the research and development of new formulation/ingredients or when the final product is ready to be marketed. For existing formulations, tests need to be carried out after changing their ingredients or modifying the percentagess of the raw materials. Besides, tests need to be carried out during quality control tests, in order to verfy the 'safety/efficacy stability' of marketed products.

Which?

Different methods can be used according to the specific requirements. In PORIM (AOTC), the tests available are as indicated. The cost of each test has not been decided yet and all requests can be directed to PORIM (AOTC), Lot 9 & 11, Jalan P/14, Seksyen 10, Bandar Baru Bangi, Selangor. Tel No. 03-8255708 and Fax No: 03-8256197.

SAF	ETY EVALUATIONS	
IN VIVO INNOCUITY		
TESTS	DESCRIPTION	
PHOTOTOXICITY	Irritation in-vivo and exposure to UV	
HYPOALLERGENICITY	Evaluation of presence of common allergen	
SKIN IRRITATION (PATCH TEST)	Skin irritation after 48 hrs. occlusion	
SKIN IRRITATION (OPEN PATCH TEST)	Skin irritation after 48 hrs. of application	
REPEATED PATCH TEST	Cycles of occlusion/removal of the product	
REPEATED APPLICATION	Repeated open application (aggressive products)	
CUTANEOUS (COMPATIBILITY EVALUATIONS	
POST (Plastic Occlusion Stress Test)	Occlusion for 24 hrs. and measure of TEWL after removal	
REPEATED WASH TEST	Repeated washes with the product and measure TEWL, colour, pH and skin roughness	
TEWL	Measure of the skin barrier properties after product use	

HAIR		
SEBUM NORMALIZING EFFECT	In use test with measures of sebum and pH	
ANTI HAIR LOSS EFFICACY	In use test with measure of hair's traction, microscopic evaluation of hair's bulb and scalp	
the state of the s	BODY HYGIENE	
DEODORANT POWER*	Sniff test after product application: evaluation of odour's reduction and length of the deodorant effect	
ANTIMICROBIC DEODORANT POWER*	Sniff test + microbiological test	
DEPILATORY EFFICACY	Capability to remove the hairs completely	

EFFICACY EVALUATIONS

SKIN PROTECTION

BARRIER EFFECT	Patch test with SLS after product application and measure of TEWL and skin colour
LENITIVE EFFECT	Measure of TEWL and the skin colour after SLS occlusion and treatment with the product
LENITIVE EFFECT (for raw materials)	Evaluation of the irritant effect of a mix of product + SLS versus SLS alone
SKIN BARRIER REPAIR	Evaluation of the skin's recovery properties after SLS application
SUN PROTECTION FACTOR (COLIPA)	Measure SPF in vivo
WATER RESISTANCE/WATER PROOF PROPERTY	Measure SPF after bath; in vivo
WATER PROTECTION FACTOR	Measure SPF in vitro

SKIN PROPERTIES IMPROVEMENT

SKIN ELASTICITY, SKIN HYDRATION, SKIN ACIDITY, SKIN SEBOMETRY	For claims as nourishing, moisturizing, for greasy/dry skin, with respect to skin pH
ANTI-STRETCH MARK EFFICACY	Capability to improve/reduce the stretch-marks aspect/appearance
ANTI-WRINKLES EFFICACY	Capability to improve/reduce the stretch-marks aspect/appearance of wrinkles
CELL RENEWAL TEST	Measure of exfoliating properties by means of Dansyl Chloride method
ANTI-COUPEROSE EFFECT	In use test with measure of micro-circulation and colour of the skin
WHITENING EFFICACY	Capability of the product to reduce/improve colour of the skin

MICROBIOLOGICAL TESTS		
TEST	DESCRIPTION	
Aerobic Plate Test	Enumeration of Acrobic Bacteria	
Yeast & Mould Plate Test	Enumeration of Yeast & Mould	
Microbial Challenge Test	To determine the effectiveness of a preservative system	
Minimum Inhibitory Concentration	To determine the minimum concentration of specific preservative effective in inhibiting microbial growth	
Identification of Microorganisms	To identify the potential contaminating microorganisms	

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