DETERMINATION OF PARABENS PRESERVATIVES IN COSMETIC AND PERSONAL CARE PRODUCTS

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Esters of p-hydroxybenzoic acid such as methyl, ethyl, propyl and butyl, commonly known as parabens are widely used as preservatives in cosmetic and personal care (CPC) products because they have a broad-spectrum anti-microbial activity, non-irritating and non-sensitizing. They are stable over wide pH range and are sufficiently soluble in water to produce the effective concentration in aqueous phase. Parabens have a good microbiocidal effect, however, they are more effective against yeast and mould than bacteria.

THE IMPORTANCE OF DETERMINATION OF PARABENS IN CPC PRODUCTS

Although parabens are widely used in CPC products, their mode of action is not well understood. They are postulated to act by disrupting membrane transport process or by inhibiting synthesis of DNA and RNA or some of key enzyme, such as ATPase and phosphotranferases in some bacteria species (Ma and Marquis, 1996).

The parabens used in cosmetic product can cause an adverse effect because of their adsorption in the bloodstream by-passes the gastrointestinal tract where they might be broken down into toxic component. A report had identified paraben as xenoestrogen, that is synthetic compound mimic the sex hormone estrogen (Routledge *et al*., 1998). Dr Oishi (2002) reported that exposure of newborn male mammals to butylparaben had adversely affect the secretion of testerone and the function of male reproductive system. Another paper stated that not only live birth and postnatal survival rates decreased among newborns whose mothers were exposed to paraben during pregnancy but also the weight of testes, seminal vesicals and prostate glands were significantly decreased (Kang, 2002). Due to the previous report of the adversed effect of parabens, the level of this preservative in CPC products should be monitored.

For cosmetic, the maximum concentration allowed is 0.4% for single ester and mixture of ester is 0.8%. In food, maximum concentration allowed is 0.1% in combination with either sorbates or sorbates and benzoates. Parabens also have a long history of use in a variety of pharmaceutical products intended for injection, inhalation, oral, rectal or vaginal administration (Soni *et al*., 2002). The maximum dosage in pharmaceutical products is 0.2%.

PARABENS TESTING SERVICES

The current method of detecting parabens in CPC products is the EU Directive Method Document 396L0045, *Identification and determination of 2-phenoxyethanol, 1-phenoxypropan-2-ol, methyl, ethyl, propyl, butyl and benzyl 4-hydroxybenzoate in cosmetic products* (EUR-Lex, 2002). Our study showed that this method was found to be unsatisfactory. A new method of detecting parabens in CPC products has been developed and this method has several advantages as mentioned below:

- simple;
- fast; and
- better accuracy.

MPOB wishes to offer the service of detecting parabens in CPC products based on the new developed method to the industry at the cost of RM 70 sample.

Companies needing this service are requested to deliver their samples (about 25 g) with a written instruction stating the test required. All samples received will be checked to ensure that they are in good condition for the analysis. The results of analysis in the form of certificate of analysis will be ready in three days.

The invoice will be sent together with the certificate of analysis. The company can use the results of analysis to monitor the level of parabens in the CPC products to comply with the maximum permissible limit set by EU regulations.

PRINCIPLE OF THE TEST

Parabens in CPC products are extracted with 45% acetonitrile-water by a vortex mixer and then heated in water bath at 60°C for 5 min. The solution is cooled in a running tap water, then it is stored in a refrigerator for an hour. The detection is by HPLC (*Figure 1*) with Apex ODS column and UV detector.

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Recoveries at 0.4% (maximum permissible limit for single paraben in CPC products) of methyl, ethyl, propyl and butyl parabens in formulated shampoo, facial cleanser, hand and body lotion, shower gel and moisturizer spiked with four esters of parabens were good ranged from 80.0% to 117.0%. Recoveries at lower level such as at 0.1% and 0.2% of these four parabens in mentioned CPC products were also good, from 86.6% to 110.4% and 86.2% to 106.1% respectively (*Table 1*).

Figure 1. HPLC for the determination of parabens in CPC products.

TABLE 1. RECOVERIES OF SINGLE PARABEN IN CPC PRODUCTS

		Concentration (%)		
Formulated product	**Paraben**	**0.1**	**0.2**	**0.4**
Shampoo	Methyl	94.4	94.8	112.0
	Ethyl	105.4	105.2	110.0
	Propyl	97.2	97.1	105.0
	Butyl	103.7	103.5	110.0
Facial cleanser	Methyl	88.6	86.2	115.0
	Ethyl	97.4	92.6	103.0
	Propyl	91.9	87.5	100.0
	Butyl	95.8	90.4	117.0
Hand & body lotion	Methyl	93.4	95.0	90.0
	Ethyl	101.3	103.6	84.0
	Propyl	93.9	95.3	80.0
	Butyl	99.0	100.0	88.0
Shower gel	Methyl	99.1	97.0	101.0
	Ethyl	110.4	106.1	100.0
	Propyl	102.3	98.7	111.0
	Butyl	109.5	105.0	112.0
Moisturizer	Methyl	86.6	87.7	110.0
	Ethyl	94.6	96.4	115.0
	Propyl	86.8	88.4	94.0
	Butyl	91.5	92.5	100.0

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