

regarding the status of pharmaceutical contamination in India¹⁷. These emerging environmental pollutants in aquatic environment may affect the biological systems of terrestrial and aquatic ecosystems^{18,19}. Further, it may act on molecules, cells and organs and pose a serious threat to aquatic organisms through unexpected modes of action^{6,20}. Therefore, their potential effects on all segments of aquatic systems, fauna and flora warrant the biomonitoring of these emerging environmental contaminants in India.

More importantly, studies on the potential adverse ecological impacts of pharmaceutical drugs and their residues on the physiology of aquatic organisms are scarce in India²¹. For instance, Malarvizhi *et al.*²² found significant alterations on enzymes in gill, liver and muscle of a freshwater fish, *Cyprinus carpio* exposed to Carbamazepine. Saravanan and co-workers^{4,10,11,21} reported toxicological effects of clofibrac acid (lipid regulating pro-drug), diclofenac (non-steroidal anti-inflammatory drug) and ibuprofen (analgesic, antipyretic and anti-inflammatory) in an Indian major carp, *Cirrhinus mrigala* and *C. carpio*. Ambili *et al.*²³ observed significant alterations on hematological and enzymological responses of an Indian major carp *Labeo rohita* exposed to oxytetracycline (antibiotic). Oaks *et al.*²⁴ found dramatic decrease in vulture (*Gyps* sp.) populations in the Indian subcontinent due to diclofenac toxicity. Thus, detailed and targeted investigations are required to study the sources, pathways and fate of the pharmaceutical drugs¹⁷.

To remove these harmful pharmaceuticals from wastewater many scientific innovations are being implemented throughout the world. Such facilities are scarce in India and they need to be developed for a healthy environment. Big cities such as Delhi, Mumbai, Kolkata and Chennai may witness health impacts in near future due to pharmaceutical drugs and their residues. Because of continuous discharge of pharmaceuticals

higher concentrations of their residues may be expected in surface water and groundwater. Hence, extensive research activities are needed to monitor the human pharmaceutical drugs in various segments of aquatic environments and on non-target organisms for better understanding of the toxicological end-point of pharmaceutical drugs.

- Gopakumar, K. M. and Santhosh, M. R., *Third World Resurgence*, 2012, **259**, 9–14.
- PricewaterhouseCoopers, http://www.pwc.in/assets/pdfs/pharma/The_changing_dynamics_of_pharma_outsourcing_in_Asia.pdf
- Cunningham, V. L., Binks, S. P. and Olson, M. J., *Regul. Toxicol. Pharmacol.*, 2009, **53**, 39–45.
- Saravanan, M., Usha Devi, K., Malarvizhi, A. and Ramesh, M., *Environ. Toxicol. Pharmacol.*, 2012, **34**, 14–22.
- Heberer, T., *Toxicol. Lett.*, 2002, **131**, 5–17.
- Fent, K., Weston, A. A. and Caminada, D., *Aquat. Toxicol.*, 2006, **76**, 122–159.
- Zuccato, E., Calamari, D., Natangelo, M. and Fanelli, R., *Lancet*, 2000, **355**, 1789–1790.
- Zhang, Y., Geisen, S. U. and Cal, C., *Chemosphere*, 2008, **73**, 1151–1161.
- Li, Z. H., Velisek, J., Zlabek, V., Grabic, R., Machova, J., Kolarova, J. and Randak, T., *Chem. Biol. Interact.*, 2010, **183**, 98–104.
- Saravanan, M. and Ramesh, M., *Chemosphere*, 2013, **93**, 388–396.
- Saravanan, M., Ramesh, M. and Petkam, R., *Fish Physiol. Biochem.*, 2013, **39**, 1431–1440.
- Shanmugam, G., Sampath, S., Selvaraj, K. K., Larsson, D. G. J. and Ramaswamy, B. R., *Environ. Sci. Pollut. Res.*, 2014, **21**, 921–931.
- Larsson, D. G. J., Pedro, C. and Paxeus, N., *J. Hazard. Mater.*, 2007, **53**, 161–163.
- Fick, J., Soderstrom, H., Lindberg, R. H., Phan, C., Tysklind, M. and Larsson, D. G. J., *Environ. Toxicol. Chem.*, 2009, **28**, 2522–2527.
- Diwan, V. *et al.*, *BMC Public Health*, 2010, **10**, 414–422.
- Ramaswamy, B. R., Shanmugam, G., Velu, G., Rengarajan, B. and Larsson,

D. G. J., *J. Hazard. Mater.*, 2011, **186**, 1586–1593.

- Rehman, M. S. U., Rashid, M., Ashfaq, M., Saif, A., Ahmad, N. and Han, J.-I., *Chemosphere*, 2013; (in press), DOI: 10.1016/j.chemosphere.2013.02.036.
- Kummerer, K., *Pharmaceuticals in the Environment. Sources. Fate, Effects and Risks*, Springer-Verlag, Berlin, 2001.
- Zuccato, E. *et al.*, *Environ. Sci. Pollut. Res.*, 2006, **13**, 15–21.
- van den Brandhof, E. J. and Montforts, M., *Ecotoxicol. Environ. Saf.*, 2010, **73**, 1862–1866.
- Saravanan, M., Karthika, S., Malarvizhi, A. and Ramesh, M., *J. Hazard. Mater.*, 2011, **195**, 188–194.
- Malarvizhi, A., Kavitha, C., Saravanan, M. and Ramesh, M., *J. King Saud Univ. Sci.*, 2012, **24**, 179–186.
- Ambili, T. R., Saravanan, M., Ramesh, M., Abhijith, D. B. and Poopal, R. K., *Arch. Environ. Contam. Toxicol.*, 2013, **64**, 494–503.
- Oaks, J. L. *et al.*, *Nature*, 2004, **427**, 630–633.

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Sun protection factor: science or advertising?

The sun has both good and bad effects on human beings. It provides warmth and light which are critical to human physical and psychological well-being. From health point of view, the sun provides

support through vitamin D synthesis, kills pathogens, phototherapy, etc.¹. The electromagnetic spectrum emitted by the sun contains 5% of UV radiations. It is essential to prevent human skin from the

deleterious effects of such radiations. There are a number of ways to do so – Sun avoidance, wearing protective clothing, hats, glasses, applying sunscreen and systemic photoprotection². A sunscreen

is defined as 'a product containing UV filters to protect the skin from solar deleterious UV-light, avoiding or minimizing the damage from radiation on human health'³. Sunscreen products incorporate different chemicals known as UV filters that absorb/reflect UV radiations. The effectiveness of marketed sunscreen products is based on sun protection factor (SPF).

SPF is a quantitative measure of the effectiveness of a sunscreen formulation. An individual SPF value for a sunscreen is the ratio of the dose of UV radiations required to produce a minimal erythema in 24 h after exposure in sunscreen-protected skin to the dose required to produce the same degree of erythema in unprotected skin of the same subject^{4,5}. According to the literature survey, *in vitro* method available for determination of SPF is as follows.

In vitro SPF can be determined for diluted solution transmittance method by UV spectrophotometer. SPF value is calculated using the equation⁶

$$\text{SPF} = \text{CF} \times \sum_{320}^{290} (\text{EE}_{(\lambda)} \times I_{(\lambda)} \times \text{Abs}_{(\lambda)}),$$

where CF is the correction factor = 10; $\text{EE}_{(\lambda)}$ the erythemogenic effect of radiation at a wavelength λ ; $I_{(\lambda)}$ the solar intensity spectrum λ ; $\text{Abs}_{(\lambda)}$ is the absorbance of sample at a wavelength λ . $\text{EE} \times I$ are constants and determined at a particular wavelength.

Another *in vitro* method used for SPF determination is the TransporeTM tape method using UV transmittance analyser^{7,8}

$$\text{SPF} = \frac{\int_{280 \text{ nm}}^{400 \text{ nm}} E_{\lambda} \cdot S_{\lambda} \cdot d\lambda}{\int_{280 \text{ nm}}^{400 \text{ nm}} E_{\lambda} \cdot S_{\lambda} \cdot T_{\lambda} \cdot d\lambda}$$

where E_{λ} is the relative erythemal spectral effectiveness, S_{λ} the solar spectral irradiance and T_{λ} is the spectral transmittance.

The UV transmittance analyser operates by measuring the diffused transmittance of a carefully prepared sample as a function of wavelength in the UV spectrum.

Several factors such as test subjects, environment, radiation source, time between sunscreen application and UV exposure, sweating, concentration of sunscreen

and vehicle, thickness of applied film, testing procedure, sunscreen type, etc. affect SPF of a sunscreen product^{9,10}. Moving towards harmonization, the international sun protection factor test method (ISPF-2003) was updated in 2006 and the same was accepted by the European, Japanese, American and South African associations of the cosmetics, toiletry and fragrance industries^{11,12}.

Sunscreens are graded based on their SPF as low (SPF value 2–15), medium (15–30), high (30–50) and highest (SPF value > 50)¹³. The current trend is to use a sunscreen product with high SPF. Sunscreen products with SPF varying from 15 to 35 are available in the market, though products claiming SPF factor of 50 or higher are also available.

In major markets, SPF range varies from country to country¹⁴. In Australia it is between 2 and 30+, Canada 2 and 30+, EU 2 and 30+, Japan 50+, New Zealand 2 and 30+, South Africa 2 and 30+ and USA 2 and 30+.

In India, sunscreens are regulated by the Drug and Cosmetic Act, under the category of cosmetics. But unlike the guidelines mentioned by the Food and Drug Administration (FDA) in the United States and major markets, India possesses no separate regulations for sunscreen products available in the market¹⁵. Though safety testing is mandatory for these products, efficacy testing is left to the manufacturers in India. However, on demand by regulatory authorities, companies need to submit proof for product claims. In the absence of specific regulatory guidelines, sunscreen products may not be stringently regulated or controlled. Hence, to advertise aggressively cosmetic companies may claim maximum SPF on the label to attract consumers. Because of the absence of stringent regulations, such false claims should not become one of the marketing tools for cosmetic companies.

The need of the hour is to frame specific regulatory guidelines by Indian regulatory authorities for sunscreen products clearly mentioning about SPF range to be claimed with efficacy proof, active ingredients, uses, warnings, directions, expiry date and other necessary information for the consumers.

1. World Health Organization, Sun protection: a primary teaching resource, 2003; <http://www.who.int/uv/publications/en/>

primaryteach.pdf (accessed on 8 October 2013).

2. Medeiros, V. L. and Lim, H. W., *Skin Ther. Lett.*, 2010, **15**(6), 1–3.
3. Salvador, A. and Chisvert, A., *Anal. Chim. Acta*, 2005, **537**(1), 1–14.
4. Osterwalder, U. and Herzog, B., *Br. J. Dermatol.*, 2009, **161**(s3), 13–24.
5. Food and Drug Administration, Department of Health and Human Services, Proposed Amendment of Final Monograph, 21 CFR Parts 347 and 352, Federal Register/Vol. 72, No. 165/Monday, August 27, 2007 Proposed Rules; <http://www.scribd.com/doc/2766591/Proposed--Rule-Sunscreen-drug-products-for-over-the-counter-human-use-proposed-amendment-of-final> monograph (accessed on 20 December 2013).
6. Mansur, J. D. S., Breder, M. N. R., Mansur, M. C. D. A. and Azulay, R. D., *Anais Bras. Dermatol.*, 1986, **61**(3), 121–124.
7. Diffey, B. L. and Robson, J., *J. Soc. Cosmetic Chem.*, 1989, **40**(3), 127–133.
8. Goma, Y. A., El-Khordagui, L. K., Boraei, N. A. and Darwish, I. A., *Carbohydrate Polym.*, 2010, **81**(2), 234–242.
9. Pathak, M. A., *J. Am. Acad. Dermatol.*, 1982, **7**(3), 285–312.
10. Kim, S. M., Oh, B. H., Lee, Y. W., Choe, Y. B. and Ahn, K. J., *J. Am. Acad. Dermatol.*, 2010, **62**(2), 218–222.
11. Colipa, C. S. and Jcia, C., 2006; <http://www.colipa.eu/publications-colipa-the-european-cosmetic-cosmeticsassociation/guidelines.html?view=item&id=21> (accessed on 16 August 2013).
12. De Paula, L. R., Parussulo, A. L., Araki, K. and Toma, H. E., *J. Pharm. Sci.*, 2012, **101**(2), 726–732.
13. Jeffries, N., <http://www.gcimagazine.com/marketrends/segments/suncare/27627099.html> (accessed on 12 November 2011).
14. Review of the regulation of products at the interface between cosmetics and therapeutic goods, 2005; <http://www.tga.gov.au/pdf/archive/consult-cosmetics-regulation-050303.pdf> (accessed on 23 November 2013).
15. Ligade, V. S., Sreedhar, D., Manthan, J. and Udupa, N., *Curr. Sci.*, 2008, **95**(3), 10.

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