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Sun production factor (SPF) determination of marketed sunscreen formulation by *In-Vitro* method using UV-VIS spectrophotometer

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ABSTRACT

The increasing consumer awareness on the risk of sun exposure related diseases like skin cancer etc., leads to the sunscreen products be approximately tested and labelled. The efficiency of the sunscreen products depends on the sun protection factor (SPF) value. Due to high cost and time consumption of in vivo SPF determination methods, in vitro methods are gaining more importance. The aim of this study is to determine the sun protection factor (SPF) of sunscreen products by ultraviolet-Visible spectrophotometry. Ten different commercially available sunscreen products of various manufactures were procured and evaluated. The repeatability of the method was tested. It is observed that the proposed spectrophotometric method is simple, rapid and repeatable for the in vitro determination of SPF values of sunscreen products.

Key words: Sunscreens, *In vitro* SPF, UV-Vis spectroscopy, cosmetic products

Abbreviations used:

SPF - *Sun protection factor*
UV-Vis - *Ultraviolet-Visible*
UV - *Ultraviolet*
STDEV - *Standard deviation*
RSD - *Relative Standard deviation*
PBSA - *Phenylbenzimidazole sulphonic acid*
BMDM - *Butyl methoxy dibenzoil methane*
OMC - *Octyl methoxycinnamate*
BENZ-3 - *Benzophenone – 3*
OC - *Octocrylene*
EHS - *2-ethyl hexyl salicylate*

INTRODUCTION

Sunlight composed of various wavelengths ranging from ultraviolet light through infrared to visible light. Exposure to solar radiation is recognized to have negative effects on the human skin. Among all, ultraviolet light is the most harmful to the skin and causes sunburns, ageing of the skin and over the long term, skin cancer [1]. UV radiation comes from sun with radiation spectrum of 200nm -400nm. The distinguished major bands are UVA (400-320 nm) and UVB (320-290 nm) and UVC (290-200 nm) [2]. Changes in lifestyle and the development of leisure activities and holiday habits, as well as tanning for cosmetic purposes either by sunbathing or by using artificial tanning devices has led to a general increase in daily exposure of the skin to ultraviolet (UV) light [3]. A consequence of this leads people to use more sunscreen products.

Due to these facts, sunscreens substances are now incorporated into day-to-day products such as moisturizers, creams, lotions and other skin care products. The regular application of these products may help to prevent the harmful effects of ultraviolet radiation to some extent. However, it is necessary that a very efficient sunscreen substance is used in the cosmetic formulation. The efficacy of a sunscreen is usually expressed by the sun protection factor (SPF), which is defined, as the UV energy required producing a minimal erythema dose (MED) on protected

skin, divided by the UV energy required to produce a MED on unprotected skin [4]. The minimal erythemal dose (MED) is defined as the lowest time interval or dosage of UV light irradiation sufficient to produce a minimal, perceptible erythema on unprotected skin [5]. The higher the SPF, the more effective is the product in preventing sunburn

$$SPF = \frac{Minimal\ erythema\ dose\ in\ sunscreen - protected\ skin}{Minimal\ erythema\ dose\ in\ nonsunscreen - protected\ skin}$$

Nevertheless, it is necessary to standardize methods to determine the SPF of commercially available products. The most traditional and officially accepted method in several countries is the *in vivo* method of determination of SPF (FDA, United States; DIN, Germany; COLIPA, European Union; AAN, Australia). All of these are long range methods and involve 10 to 20 human volunteers of both sexes, with appropriate skin types. The *in vivo* method is expensive and introduces the ethical consideration of human testing [6]. As a result of this, scientists were putting efforts to develop an *in-vitro* technique in assessing the efficiency of sunscreen products.

The *in-vitro* approaches are generally two types. 1) Measurement of absorption or the transmission of UV radiation through sunscreen product films in quartz plates or membranes 2) methods in which the absorption characteristics of the sunscreens agents are determined based on spectrophotometric analysis [7]. Mansur *et al.* developed a very simple mathematical equation to estimate the sun protection factor by *in-vitro* method using UV spectrophotometry [8]. The major advantage of the *in vitro* test is that it is a rapid, objective, cost-effective screening methodology. *In vitro* testing can be used as a formulation tool to identify new filters, optimize combinations of old ones, and pre-screen protective formulas prior to *in vivo* testing in humans.

The aim of this study is to determine the sun protection factor (SPF) of commercially available skin creams by ultra violet spectroscopy and compare the results with the label claimed SPF values. Also, assess the repeatability as well the possibility to use as a regular quality control method for marketed sunscreen products.

MATERIALS AND METHODS

Reagent: Ethanol (HPLC grade)

Instrument: Double beam Shimadzu UV-Vis spectrophotometer equipped with 1cm quartz cell and computer

Samples: Commercially available, sunscreen material incorporated fairness/anti-aging creams of ten different products were purchased from the local market. These samples having the claim of SPF ranging from 15 to 30

Sample preparation

Weigh about 1.0g of the sample in a 100mL volumetric flask and add ethanol about 3/4th volume of the flask. Sonicate the contents for about 10 minutes and make up to the mark using ethanol. Filter the solution through whatman No1 filter paper and collect the filtrate by rejecting the first few mL of the filtrate. Take 5mL of the aliquot in a 50mL volumetric flask and make up to the mark using ethanol. Then take 5mL of the diluted solution in to the 25mL volumetric flask and made up to the mark using ethanol [9].

The absorption spectra of sample solution were obtained in the range of 250 to 400 nm using 1 cm quartz cell, and ethanol as blank. The absorption data were obtained in the range of 290 to 320, every 5 nm, and 3 determinations were made for each samples.

The SPF of the samples were calculated using the below equation (a mathematical expression derived by Mansur) and the relationship between erythemogenic effect and radiation intensity at each wavelength, (EE X I) was determined as described by Sayre [10] (Table I).

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

Where: EE – erythemal effect spectrum; I – solar intensity spectrum; Abs - absorbance of sunscreen product; CF – correction factor (= 10). The values of EE x I are constants and Sayre et al determined them.

Table I. Relationship between erythemogenic effect and radiation intensity at each wavelength

Wavelength	EE X I
290	0.0150
295	0.0817
300	0.2874
305	0.3278
310	0.1864
315	0.0839
320	0.0180
Total	1

RESULTS AND DISCUSSION

In this research, ten different commercially available sunscreen products labelled from sample A to sample J were evaluated by UV –visible spectrophotometry applying Mansur mathematical equation. The repeatability of the method was tested by analysing the sample H (Labelled SPF value is 15) five times and the results are shown in table II. The table II shows that the standard deviation 0.03 and the percentage relative standard deviation is 0.21. This result clearly indicates that the method is highly repeatable

Table II: Repeatability of the method

Replication	Observed SPF
1	14.73
2	14.78
3	14.81
4	14.79
5	14.76
Average	14.77
STDEV	0.03
%RSD	0.21

The SPF value of ten different commercially available products results are shown in table III along with the information related to the presence of active ingredient, labelled SPF value and the difference between the labelled SPF and the observed value.

Table III. Observed and labelled SPF in the market samples.

S.No	Sample details	Active ingredient from label declaration	Labelled SPF	Observed SPF ±STDEV	difference from original
1	Sample A	PBSA, BMDM, OMC	15	14.03±0.08	0.97
2	Sample B	PBSA, OMC	15	15.28±0.05	- 0.28
3	Sample C	Benz-3, OMC	20	13.95±0.08	6.05
4	Sample D	PBSA, BMDM, OMC	20	19.41±0.05	0.59
5	Sample E	PBSA, BMDM, OC, OMC	20	12.11±0.01	7.89
6	Sample F	PBSA, BMDM, OC, EHS	15	14.18±0.05	0.82
7	Sample G	Benz-3, OC, BMDM,EHS	30	22.22±0.02	7.78
8	Sample H	OMC	15	14.77±0.03	0.23
9	Sample I	PBSA, BMDM, OC, EHS	24	23.12±0.09	0.88
10	Sample J	PBSA, BMDM, OC, EHS	24	23.31±0.01	0.69

From the table it is observed that sample A, B, D, F, H, I and J shows closer agreement between the labelled SPF value and the observed SPF value. The differences between the labelled and observed SPF values are 0.97, -0.28, 0.59, 0.82, 0.23, 0.88 and 0.69 respectively. Sample G shows about 7.78 difference from the labelled SPF. The labelled SPF of sample G is 30. This claim indicates that the amount of sunscreen materials probably higher compared to other products. According to Pissavini *et al.* [11], a high SPF values are more difficult to measure. A high SPF normally leads to a greater uncertainty also in the final *in vivo* result, due to the biological variations of the volunteers. The sample C and E shows 6.05 & 7.89 difference respectively from the labelled SPF. These data variations can be due to the various reasons like the type of emulsion used for the formulations, the effects and interactions of vehicle components, the pH system and the emulsion rheological properties, use of different solvents in which the sunscreens are dissolved etc., can increase or decrease UV absorption of each sunscreen. Excipients and other active ingredients can also produce UV absorption bands, thus interfering with those of UVA and UVB sunscreen.

The effect that different solvents and emollients have upon the wavelength of maximum absorbance and upon the UV absorbance of several sunscreens chemical alone or in combination is well known and documented [12].

Hence before studying the SPF value of sunscreen products by *in-vitro* method, scientist should understand not only the UV absorbance of the actives, but also vehicle components, such as esters, emollients and emulsifiers used in the formulation.

CONCLUSION

The propose *In-vitro* SPF determination method is simple, rapid and can be used for many types of cosmetic formulations. This UV –Vis spectrophotometric method also useful to the formulator as pre-screening and predictive tool prior to the *in-vivo* test when optimising the formulation with new sunscreen ingredients or changing the compositions and combinations. This method can be used as a rapid quality control method during the manufacturing processes.

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