Sincere and reliable SPF: a quality process that can be deployed worldwide

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Abstract

Sunlight can be harmful to all skin tones when adequate protection is not used. Many biological and clinical effects are associated with the improper sun exposure and the use of sunscreen may prevent the skin damage. The level of sun protection provided by a product has traditionally been proven using standardized and harmonized *in vivo* methods. However, despite the standardization, variability may be observed in the results.

To bring products to the market with a sincere and reliable SPF claim is the key to insure consumer protection all around the world. Focusing on this, our Group put into place a quality process, developed worldwide with our partners a high collaborative work in order to get the sincerest and most reliable SPF, with the same global high level of quality, respecting the different local regulations. This quality guidance allows us to enhance reliability of SPF studies worldwide while deploying a high level of quality assurance and control, avoiding potential risks to consumers' health, and claiming sincere SPF. This quality process is applicable for others *in vivo* photoprotection indices, such as UVA-PF or Water-resistance.

Keywords: SPF; *in vivo*; Quality; Sincerity; Claim;

Background

Historically, sunlight has been considered a source of life. However, exposure to sunlight without proper protection is directly harmful for all skin tones and has been associated with biologic and clinical effects such as burning, tanning, photoaging and

photocarcinogenesis. The use of sunscreens prevents these outcomes by scattering, reflecting or absorbing the UV light.

The determination of a sunscreen's efficacy is essential to quantify its effectiveness in preventing skin damage and illustrates its clinical benefit. The level of sun protection provided by sunscreen products has traditionally been proven using standardized and harmonized *in vivo* methods, which use the evaluation of biological end points, triggered by solar radiation.

The Sun Protection Factor (SPF) is an international reference to express the protection from erythema, mostly due to UVB rays. It is used for labelling purposes to help consumers to make the appropriate choice for the proper level of protection. The Sun Protection Factor is one of the rare cosmetic claims which is determined through standardized methods, such as the globally adopted ISO 24444:2019 standard [1] or FDA 2011 (revision ongoing) OTC sunscreen monography [2]. These standards provide a controlling frame regarding the different aspects of the method, from the required equipment specifications, the procedure to determine the SPF, passing the test subject inclusion criteria, the use of reference samples, the sunscreen application, UV exposure and erythema readings.

Despite the standardization, variability in results can be observed [3]. This variability could be explained by different experimental conditions, factors in volunteer' selection, product application procedures, visual assessment of erythema… Moreover, the sun protection factor is related to health products. This underscores the importance of bringing products to the market with sincere and reliable SPF claims that ensure consumer protection. In this context, the quality process is a mandatory part, preparing us and the CROs for all critical steps aimed at improving the quality, safety and efficacy of sunscreens as an important part of consumer protection.

The intention of this communication is to describe the quality process our Group developed alongside our partners. It is a highly collaborative work effort we are using to achieve the sincerest and most reliable SPF globally, with a high level of quality, and respecting the different local regulations.

Methods

The photoprotection quality process is based on at least two important strategies:

The first one, internally, is an international Photoprotection Community created within the R&I teams of our Group with strong local anchorage. This community built and deployed a strategy with global rules and universal measurements, respecting the local regulation and following a common objective of quality and sincerity of claims.

The key point of this strategy was to develop a common process of selection and validation of a new vendor to integrate into our worldwide core list of CRO's, as well as to remain vigilant to ensure the quality level of the validated vendors over the time.

The second one, externally, working with the CROs. The main points of this process take into account each step of the SPF study's protocol and are aligned with the frame of both ISO24444 and FDA methods. The key points are:

- Inclusion of volunteers: skin color homogeneity, test area quality;
- Dispensing and formula application: checking the spreading and homogeneity of the product and having technicians trained and validated on the proper application. This is achieved initially through "digital" monitoring, and later the final technician validation is done in situ as part of the process.
- UV Exposures and controls: deploying measurements of fluxes before each exposure,
- Readings: Initially the technicians are trained and validated using MED atlases, and the final validation is done *in situ* as part of process. In addition, ring tests are performed systematic with the CROs.
- System quality audit: audits on the quality process are performed by checking its process, the compliance obligations and adjustments in terms of Good Practices, with emphasis on GLP and GCPs.
- Final Validation Process confirmation: a blinded study using internal reference formulas is performed, observing all steps described, as well as the final SPF results expected for our internal reference.
- Surveillance: following an internal action plan, formulas whose SPF are well known are regularly added, in order to validate the test results for the products.
- Quality Maintenance: periodic training, monitoring, audits and ring tests are kept used as part of Photoprotection CROs Quality Plan.

Results and Discussion

Through this worldwide community, key steps of a robust quality process which meets both ISO and FDA specifications were identified and deployed with our partners, ensuring more reliable SPF results. These key steps cover each of the method specifications required in both standards. In building this globally harmonized process, we incorporated as many checkpoints as possible, incorporating the best of each method as long as it was consistent within the others. For example, for the inclusion of test subjects, we consider the homogeneity of skin color and the quality of the test area using ITA° as requested in ISO24444, which is not specified by the FDA method today but is completely within its framework nevertheless.

To deploy this process in a new CRO for integrating them into the Core List requires time and resources from both parts. The global timing depends on the initial experience of the testing laboratory and on the time our internal Photoprotection Community can dedicate to this process. On average we devote over one year for a new CRO to complete the full process. To optimize the resources and adapt to the altered work and travel conditions of the past 2 years, most of the steps were developed to be compatible with remote monitoring conditions. Thus, all the training and initial validation for dispensing and application and for MED reading can be performed remotely by the monitor, yet the final validation is still done in situ.

This approach has helped to reduce the variability that we have observed in the past and increases the robustness of the test results on our products. Such impact is unfortunately quite difficult to evidence. Before this deployment we missed key quality indicators, other than the use of the sunscreen reference product requested in the standards, which is an important yet limited way to validate a test result. The absence of such indicators is a strong limitation for quantifying the impact of our process, and we are working toward defining some. As a first step, surveillance through well-known formula allowed us to consider the z-score as an additional quality criterion in our studies [4].

This procedure has become a key element of the collaboration between our Group and the CROs of our Core List, reinforcing the win-win partnership through its positive influence for both parties. From our perspective, we appreciate the fluidity brought to the

monitoring of our studies and the confidence in the results provided. From the CROs' side they are pleased with the increased quality of their positioning in the inter-laboratory campaigns organized by BIPEA. The increasing number of laboratories participating in the inter-laboratory proficiency campaign organized by BIPEA or FEBEA may indicate that such Quality pathway is far from being an isolated initiative, and that to better control the test quality and reinforce SPF test results is a common, shared concern and purpose in the global Cosmetics industry [5].

To formalize this approach and share these results with all the teams in charge of conducting SPF testing, a “Sun Barometer” of CROs was deployed, and regularly updated thanks to systematic monitoring done of the CROs of the Core List. This document aims to gather and summarize all information relevant to our product being tested in reliable conditions, including but not limited to the regulatory frame for each country, which CRO is qualified to perform which method, and where they are in the validation and/or maintenance processes.

The procedure is continuously optimized and improved to follow the revision of the standards, but also by the feedback and exchanges with the CROs. Thus, we entered in a virtuous circle as all of this work performed on data quality allows us to be a source of proposal in industry associations and standardization bodies such as Cosmetics Europe, FEBEA, PCPC, ABHIPEC, ISO, ABNT.

Conclusion

In conclusion, this quality guidance put in place by our Group, in partnership with our vendors, allows us to enhance the reliability of the SPF worldwide. We accomplish this while respecting local regulation and deploying a high level of quality control, thus avoiding any risk to the consumer’s health, and results in claiming sincere SPF. This quality system, which we described here for the SPF measurement, is applicable for the other in-vivo photoprotection indices and methods, such as UVA-PF and Water-resistance. Aadditionally, it is a useful source for analyzing the functioning and improvements to the process, providing a more accurate identification of risks, and leading to the development of more effective action plans in the future.

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