SUN PROTECTION FIELD – REFERENCE PRODUCT

Compliance control of reference product following

ISO 24443:2012 – FDA monograph 2011 – Boots Star Rating System 2011 for in vitro

ISO 24444:2010 – ISO 24442:2011 – FDA monograph 2011 for in vivo

SUNCERT

43 rue Condorcet
60700 PONT-SAINTE-MAXENCE
France
Email: contact@suncert.fr
Website: www.suncert.fr

Version: PARTNER-PRODUCT-V1

Agenda

SUN PROTECTION FIELD – REFERENCE PRODUCT

Summary

Beyond the certification of the competence of laboratories assessment of sun protection, it is important to have confidence in the conformity of equipment, consumables and services provided by suppliers with standards and methods.

For this, each product (equipment and consumable) and service (calibration and interlaboratory campaign) shall meet a complete technical specification extracted from the standards and methods.
In addition, each batch/serial certificate of these products/services should be also checked to ensure sustainability of compliance.

REFERENCE PRODUCT	
Type:	Sun protection field – Reference product
Goal(s) and scope(s):	Check the quality and technical specifications of a reference product to comply with in vitro and in vivo sunscreen testing methods
Reference(s):	In vitro: ISO 24443:2012 - FDA monograh 2011 - Boots Star Rating System 2011 In vivo: ISO 24444:2010 – ISO 24442:2011 – FDA monograph 2011

DOCUMENT	
Reference:	PARTNER-PRODUCT-V1
Creation date:	24/02/17
Revision date:	14/02/18
Content:	1. General control 2. Technical control
Status:	Applicable
Editor(s):	Sébastien MIKSA (SUNCERT)

Steps

General control

To ensure a minimum quality level, the inspected company should have a quality system management.

At least one Certification / Label is required.

Note: If none is available, a complementary audit should be necessary including management system, subcontracting services, control of records in general and technical, internal audits, management reviews, equipment, accomodation and environment, confidentiality, etc.

Technical control

The second part concerns the technical characteristics inspection of the reference product dedicated to the sun protection field.

For the technical part, the control results, used protocols and associated certificates (if applicable) are required to be valid.

General control

Subject	Yes	No	NA /NE	Comment
1. GENERAL				
1.1. *Certification / Label*				
➢ ISO 9001				
➢ ISO 13485				
➢ ISO 17025				
➢ ISO 17043				
➢ FDA registred				
➢ GMP (Good Manufacturing Practice)				
➢ GLP (Good Laboratory Practice)				
➢ GCP (Good Clinical Practice)				

Technical control

Subject	Limit	Yes	No	NA /NE	Comment
2. REFERENCE PRODUCT					
2.1. *General*					
➢ Packaging	Ideally several bottles to avoid contamination and deterioration during sampling. Container protecting from light and inert towards all ingredients of the reference product				
➢ Storage	12 months at 20°C from manufacturing date protected from sun light				
2.2. *Technical*					
➢ Analytical specifications	**P2** - 7.0% of ethylhexyldimethyl PABA (CAS 21245-02-3) (2-ethylhexyl-4- (dimethylamino) benzoate) - 3.0 % of benzophenone-3 (CAS 131-57-7) **P3** - 3.0% of ethylhexyl methoxycinnamate (CAS 5466-77-3) (2-ethylhexyl-4-methoxycinnamate) - 0.5 % of butylmethoxydibenzoylmethane (CAS 70356-09-1) - 2.78 % of phenylbenzimidazole sulfonic acid (CAS 27503-81-7) (2-phenylbenzimidazole-5-sulphonic acid) **P7** - 8.0% of Homosalate (CAS 118-56-9) **S1** - 3.0% of ethylhexyl methoxycinnamate - 5.0 % of butylmethoxydibenzoylmethane **S2** - 3.0 % of octocrylene - 5.0 % of butylmethoxydibenzoylmethane - 3.0% of ethylhexyl methoxycinnamate - 2.0 % of bis-ethylhexyloxyphenol-methoxyphenyl triazine				
➢ Physical-chemical specifications	**P2** pH [8.0 ± 0.5] Viscosity [19 000 mPa.s – 33 000 mPa.s] Density [0.970 ± 0.05 g/cm^3] **P3** pH [7.5 ± 0.5] Viscosity [2 000 mPa.s – 4 000 mPa.s] Density [0.970 ± 0.05 g/cm^3] **P7** pH [8.0 ± 0.5] Viscosity [1 000 mPa.s – 3 000 mPa.s] Density [0.970 ± 0.05 g/cm^3] **S1** pH [6.5 ± 0.5] Viscosity [50 000 cP – 80 000 cP] Density [0.95 ± 0.05 g/cm^3] **S2** pH [6.5 ± 0.5] Viscosity [7 000 cP – 12 000 cP] Density [0.98 ± 0.02 g/cm^3]				

➢ Clinical specifications	Ideally at least evaluation the skin irritant potential after single application under patch				
➢ Sun protection specifications	**Ideally to be tested for each batch** **P2** ISO 24444:2010 – In vivo SPF [13.7 – 18.5] FDA monograph 2011 – In vivo SPF [12.87 – 19.73] **P3** In vivo SPF [13.7 – 17.7] **P7** In vivo SPF [4.0 – 4.8] **S1** In vivo UVAPF [3.8 – 5.0] **S2** In vivo UVAPF [10.7 – 14.7]				
2.3. *Control*					
➢ Certificate	Per batch, a quality certificate including (i) the measured results of each UV filter(s) percentage, pH, viscosity at 20°C (mPa.s or cP), density at 20°C (g/cm^3), (ii) the control date of raw material, manufacturing, physical-chemical characteristics, clinical and analytical and (iii) the measured in vivo sun protection values (when applicable)				
➢ Analytical	The formulation is gravimetrically sampled and dissolved in methanol/ethanol (in which the analytes are soluble). The solution is diluted with a mobile phase of HPLC chromatography and analyzed by reverse phase HPLC chromatography. The concentrations of the analytes in the sample are determined by quantification against a mixed external standard solution of raw materials to be analyzed. Analytical results are acceptable if the following conditions are met: a) the standard coefficient of variation is u 2.5%; (b) the salvage value is 100% ± 5% for all active ingredients; c) absence of interference of chromatographic peaks.				