

SUN PROTECTION FIELD - SOLAR SIMULATOR

*Compliance control of solar simulator appliance following
ISO 24443:2012 – FDA monograph 2011 – Boots Star Rating System 2011 for in vitro
ISO 24444:2010 – ISO 24442:2011 – FDA monograph 2011 – JCIA 1999 for in vivo*

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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 or each calibration of these products should be checked to ensure sustainability of compliance.

SOLAR SIMULATOR	
Type:	Sun protection field – Solar simulator
Goal(s) and scope(s):	Check the quality and technical specifications of solar simulator to comply with in vitro and in vivo sunscreen testing methods
Reference(s):	In vitro: ISO 24443:2012 - FDA monograph 2011 - Boots Star Rating System 2011 In vivo: ISO 24444:2010 – ISO 24442:2011 – FDA monograph 2011 – JCIA 1999

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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, accommodation and environment, confidentiality, etc.

Technical control

The second part concerns the technical characteristics inspection of the appliance 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 – In vivo

Subject	Limit	Yes	No	NA /NE	Comment
2. SOLAR SIMULATOR – In vivo part					
2.1. Component					
➤ Solar simulator with a continuous spectrum	Xenon arc Lamp recommended				
➤ UV exposure of all spots simultaneously	Recommended				
➤ Spot form	Circle but rectangular form preferred				
➤ Heating feeling	Confirmation that the solar simulator won't induce excessive heating feeling				
2.2. Technical					
➤ Beam uniformity	<10% of uniformity between each spot for time variation having large beam (single port) or check all beams for dose variation having light guides or multiple spot beams (multiport)				
➤ Respect of the limits of the Percentage Relative Cumulative Erythmal Effectiveness (%RCEE)	ISO 24444:2010 – FDA monograph 2011 [<290nm: - to < 0.1]; [290-300nm: 1.0 to 8.0]; [290-310nm: 49.0 to 65.0]; [290-320nm: 85.0 to 90.0]; [290-330nm: 91.5 to 95.5]; [290-340nm: 94.0 to 97.0]; [290-400nm: 99.9 to 100.0]				
➤ Respect of radiometric proportion	ISO 24444:2010 – FDA monograph 2011 UVA II lighting > 20% and UVA I > 60% of total UV lighting (290-400nm) ISO 24442:2011 [<320nm: <0.1% of UV light]; [320-340nm: 8 to 20% of UVA light]; [340-400nm: 80 to 92% of UVA light]; [400-1500nm: <5% of UV, visible and near infrared] JCIA 1999 Ratio of UVAII/UVA = 8 to 20% and exclusion of UV light shorter than 320 nm, visible and infrared light				
➤ Irradiance level	ISO 24444:2010 < 1600 W/m ² for 250 - 1400 nm FDA monograph 2011 < 1500 W/m ² for 250 - 1400 nm ISO 24442:2011 < 1600 W/m ² for 290 - 1500 nm				
2.3. Complementary					
➤ Identification report	Document of calibration provided with appliance has to include at least: - Appliance model and Serial number - Date of control, Operator and Company name - Equipment used - Results of calibration, Spectrums and Values				
➤ Traceable calibration of emission by spectroradiometric measurements by a suitably qualified expert	If calibration performed by a Certified Partner, none further control will be done. Please provide the spectroradiometric measurement report or at least the certificate indicating the Certified Partner.				
	If calibration performed by anyone else, please refer and complete the "Certified Partner in sun protection field: Spectroradiometric Calibration".				

Technical control – In vitro

Subject	Limit	Yes	No	NA /NE	Comment
3. SOLAR SIMULATOR – In vitro part					
3.1. Component					
➤ Solar simulator with a continuous spectrum	Xenon arc Lamp recommended				
➤ Irradiance spectrum	ISO 24443:2012 As similar as possible to the irradiance at ground level under a standard zenith sun FDA monograph 2011 As similar as possible to the irradiance used during in vivo SPF test				
➤ Heating	Confirmation that the solar simulator won't induce > 2°C variation during exposure step				
➤ Placing samples system	UV source no switches off while placing samples under the lamp				
➤ Air flow	Appliance should not induce air flow on the sample during irradiation step				
3.2. Technical					
➤ Respect of the limits of the Percentage Relative Cumulative Erythral Effectiveness (%RCEE)	FDA monograph 2011 [<290nm: - to < 0.1]; [290-300nm: 1.0 to 8.0]; [290-310nm: 49.0 to 65.0]; [290-320nm: 85.0 to 90.0]; [290-330nm: 91.5 to 95.5]; [290-340nm: 94.0 to 97.0]; [290-400nm: 99.9 to 100.0]				
➤ Respect of radiometric proportion	ISO 24443:2012 Irradiance UVA:UVB ratio between 8 – 22 FDA monograph 2011 UVA II lighting > 20% and UVA I > 60% of total UV lighting (290-400nm) BOOTS STAR RATING SYSTEM 2011 UVA irradiance level between 90% and 97% of total irradiance				
➤ Irradiance level	ISO 24443:2012 Between 40 – 200 W/m ² from 290 to 400 nm FDA monograph 2011 Less than 1500 W/m ² from 250 to 1400 nm BOOTS STAR RATING SYSTEM 2011 Between 45 – 90 W/m ² from 290 to 400 nm				
3.3. Complementary					
➤ Identification report	Document of calibration provided with appliance has to include at least: - Appliance model and Serial number - Date of control, Operator and Company name - Equipment used - Results of calibration, Spectrums and Values				
➤ Traceable calibration of emission by spectroradiometric measurements by a suitably qualified expert	If calibration performed by a Certified Partner, none further control will be done. Please provide the spectroradiometric measurement report or at least the certificate indicating the Certified Partner.				
	If calibration performed by anyone else, please refer and complete the “Certified Partner in sun protection field: Spectroradiometric Calibration”.				