

# SUN PROTECTION FIELD - SPECTROPHOTOMETER

*Compliance control of spectrophotometer appliance following  
ISO 24443:2012 – FDA monograph 2011 – Boots Star Rating System 2011*

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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 of these products/services should be also checked to ensure sustainability of compliance.

SPECTROPHOTOMETER	
<b>Type:</b>	Sun protection field - Spectrophotometer
<b>Goal(s) and scope(s):</b>	Check the quality and technical specifications of spectrophotometer to comply with in vitro sunscreen testing methods
<b>Reference(s):</b>	ISO 24443:2012 FDA monograh 2011 Boots Star Rating System 2011

DOCUMENT	
<b>Reference:</b>	PARTNER-SPECTRO-V3
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## **Steps**

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### **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
<b>1. GENERAL</b>				
<i>1.1. Certification / Label</i>				
➤ 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
<b>2. SPECTROPHOTOMETER</b>					
<b>2.1. Component</b>					
➤ Lamp	Xenon Flash Lamp recommended				
➤ Ozone generation	No				
➤ Data Input/Output	≥ 16-bit data of resolution acceptable				
➤ Path length	≤ 5 mm (recommended ≤ 3 mm) for distance between spectrometer / detector – sample - integrating sphere output / input				
➤ Stage position	Automatic recommended				
➤ Blank measurement	Automatic calculation recommended				
➤ Integrating Sphere size	Size at least 100 mm				
➤ Integrating Sphere material	High diffuse reflectance [Polytetrafluoroethylene (PTFE), Indium Gallium Arsenide (InGaAs), Lead Sulfide (PbS), etc.]				
<b>2.2. Technical</b>					
➤ Wavelength range	At least 290 – 400 nm				
➤ Wavelength step	≤ 1 nm				
➤ Spectral FWHM Bandwith	≤ 2nm (up to 4nm may be used if material evaluated has a continuous and non-erratic absorbance profile)				
➤ UV Dose	≤ 0.2 J/cm <sup>2</sup> per measurement cycle				
➤ Peak Accuracy in UV range	≤ 1 nm from referenced peak				
➤ Absorbance Range in UV range	≥ 2.2 AU (recommended 3.0 AU)				
➤ Linearity test	≥ 90% of the dynamic range				
➤ Stray Light	-				
➤ Noise level / Dark Current of detector	≤ 0.20% of the peak signal being measure at each wavelength				
➤ Repeatability Measurement	≤ 0.5% of referenced material				
➤ Heating Temperature	≤ 0.2°C per plate measurement				
➤ Reading Area	≥ 0.5 cm <sup>2</sup> per measurement cycle				
<b>2.3. Complementary</b>					
➤ Control Kit	a) Physical Filters at least 4 levels: ≈ 0.5% T; ≈ 5% T, ≈ 10% T and ≈ 25%T b) Dual Doped PMMA plates for Dynamic/Linearity test (absorbance peak at 340 nm between 1.1 - 1.5 AU)				
➤ Software	Calculations explanation of the different methods available with data sample example: <ul style="list-style-type: none"> <li>- SPF (SSR, Albuquerque, Melbourne...)</li> <li>- UVA-PF (ISO 24443, Colipa 2011)</li> <li>- Critical Wavelength (FDA 2011, ISO 24443, Colipa 2011)</li> <li>- UVA:UVB ratio (Boots Star Rating System 2011)</li> </ul>				