

KBF series with ICH compliant illumination & Light Quantum Control:

Environmental simulation chambers for constant climatic conditions with light plus sophisticated light measurement, realistic light exposure calculation & automated light processing.

The requirements of ICH-Q1B:

- ▶ ICH Q1B recommends an actinometric system for monitoring of the radiation exposure. An actinometer is a glass ampulla filled with a photosensitive solution
- ▶ Over the volume expansion of the actinometer the photochemical sensitivities in - volume expanded - pharmaceutical products are simulated best possible and directionally independent
- ▶ The radiation exposure is correlated to the conversion of the chemical photo reaction taking place.



BINDER's unique solution – LIGHT QUANTUM CONTROL:

- ▶ The only - physically correct - way for an electronic simulation of an actinometric system is the **Spherical Measurement with Integration** → BINDER's **LIGHT QUANTUM CONTROL**

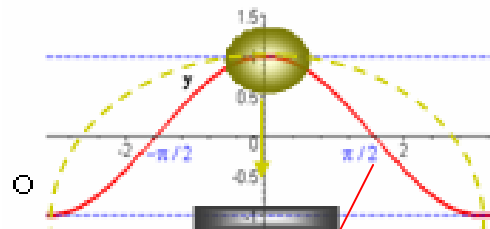
- ▶ Compared to planar (cosine adapted) sensors,

spherical sensors measure to a great extent directionally independent. They are suitable for all kinds of samples with spatial extension or spatially distributed objects (e.g. bottles and other vessels, pills, dissolved substances).

Here, the radiation intensity or illumination really entering the sample can be realistically determined with spherically measuring light sensors.

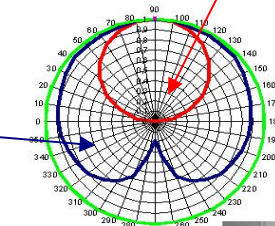
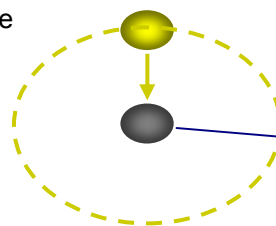
The energy entering the sample in the visible, and UV range is thus weighted in optimal approximation to its real photochemical effects.

Planar Sensors: Cosine Adapted



- ▶ Use of spherical sensors in the BINDER measurement system imitates the quantification of the photochemically effective radiation in optimal approximation and allows an exposition exactly responding to the demands of the ICH guideline Q1B

Spherical Sensors: Directionally Independent

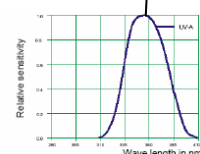
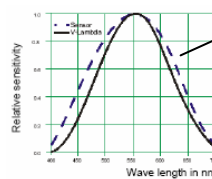


Ideal spherical sensitivity characteristics

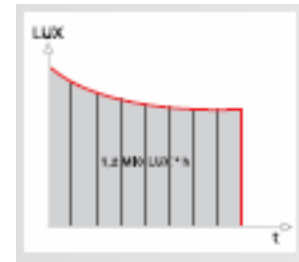
- ▶ The spherical sensors measure the light intensities as follows:

The relative spectral sensitivity of the sensor for visible light is the V-λ distribution according to the sensitivity characteristics of the human eye.

The UVA sensors must consider the spectral range defined in ICH guideline Q1B, Option 2 as between 320 and 400 nm.



- ▶ For both the visible and UV light the correctly measured intensities are continuously integrated.
The integration of the correct light intensity over time allows to calculate the correct and realistic light exposure dosage rate.



- ▶ The actually integrated light dosages are compared to setpoints individually settable for visible and UV light.

The display can be switched alternatively between displaying the light intensities being actually measured or the actually integrated light dosages.

	W	X	
TEMP	25.0	25.0	°C
HUMID	60.0	60.0	%RH
VIS	1.2	0.9	
UVA	200.0	173.6	
DOS E8 MLUXh Wh/sqm			
HAND			
CONFIG	PGM	W	VIEW->

- ▶ Upon reaching the setpoints the lights are switched off automatic and separately for visible and UV light
- ▶ As the spherical sensors are flexible and movable over the entire inner chamber the light intensities are measured at sample location. This is a requirement of ICH-Q1B!



In summary we call this innovative technology LIGHT QUANTUM CONTROL:
As it allows to control automatically the amount or *quantum* of light to which the test specimen are exposed to.

- ▶ Without saying one more proof of BINDER's innovation potential this unique feature is of course patented.



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