# White Paper for Photo Stability

Photo stability testing is important in developing and manufacturing a wide range of products for some or all of the following reasons. Outside of the necessary guidelines, unfavorable appearance, recessive or misaligned efficacy, physical changes, chemical changes, and microbiological changes are some the important factors that must be looked at.

Stability testing is very important to establish the integrity that a product has to environmental changes. This involves a variety of different parameters specifically VIS and UV light. The ability to duplicate these parameters will create the benchmark for which subsequent testing is done on the same product of different lots or batches. A key aspect in photo stability is to duplicate the exposure of the light to the product or active ingredient. A major part in duplicating conditions is the ability to check the conditions with an appropriate device that can measure the light exposure.

Light is emitted in 3 dimensions and therefore needs to be measured in 3 dimensions and requires a device that will do so. Currently there are 2 types sensors used to measure light. One is planar and the other is spherical both types are used to measure the spectrum of UV and VIS light. (Pease see pictures on below.)

## Spherical Sensor (Binder UV&VIS)

## Planar type Sensor (Atlas Xenocal)

The planar (cosinus adapted) type which value's the exposure direction which does not coincide to the photochemical effect in a volume expanded system. Thus this sensor would only measure from a vertical perspective. This would mean that the light measured would is less than the light emitted.

The other sensor available is the spherical sensor. This will measure light intensity almost independent from the angle of incidence of the light and therefore simulate the photochemical sensitivities of (volume expanded) products electronically in best approximation. This means that it will best detect the light in 3 dimensions, as would a product on the shelf be exposed to light.



**BINDER Inc.** ► 3500 Sunrise Highway / Ste D214 ► Great River, NY 11739 – Phone (631) 224 4340 – Fax (631) 224 4354 – Toll Free (866) 885 9794

The ICH also has suggested a actinometric procedure for monitoring exposure to as near UV fluorescent lamp. This involves a ampoule and filling it with a specified solution and exposing it to the light as well as control ampoule. This is a disposable method which also requires setting up the chemical reaction.

When following the accepted ICH guideline Q1B which is recommended by the FDA CDER for testing of new drug substances and products or the FDA recommended VICH (International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products) this is the only physically correct way for an electronic simulation is the spherical measurement with integration. Please see the picture at the end.

When considering the light sensor it is important to recognize that the Planar sensor may underestimate the light exposure and cause over exposure of the product which may cause it not to pass and delay an FDA approval. The Spherical sensor with correct integration will provide accurate knowledge of product sensitivity to light.

As it is also important to use UVA detectors measuring the emitted radiation spectral correctly, spectral sensor sensitivity and emitted UV spectrum have to be adapted to each other. Binder UV sensors have a spectral sensitivity adapted exactly to the UVA florescent tubes we use. Spectral emission curve of the florescent tube and spectral sensitivity characteristic curve of our UVA sensor are nearly congruent.

When using a non fixed spherical sensor that is placed near the product actual light intensities can be determined at the sample location as well as integrated light dosages. In determining actual dosages of light it is also important to set separate set points for the UV and VIS light sources which is controlled by the stability chamber's integrated control panel.

When controlling the light exposure it is also important to maintain the temperature and humidity conditions through out the chamber. The heat generated by the light source can not be an uncontrolled variable and create uniformity issues. This would intern create micro climates within the chamber and not give reliable and uniform results.

In conclusion we must also look at the lighting source and does it follow ICH Q1B guidelines. The necessary guidelines as recommended by the FDA. These guidelines will simplify testing by using guidelines that are already accepted. The guidelines for light are 1.2 Mio. Lux hours (visible light) light white color at 20 at sample position. For UV light is 200Wh/m^2 UVA intensity at sample. This criteria in mind it is easy to see that at sample position incorporates that fact the sample is dimensional and so must the measurement of light.



**BINDER Inc.** ► 3500 Sunrise Highway / Ste D214 ► Great River, NY 11739 – Phone (631) 224 4340 – Fax (631) 224 4354 – Toll Free (866) 885 9794

For further information please contact:
Binder Inc.
Ron Breuer (631)224-4340 ext.116 or ronald.breuer@binder-world.com
Binder Inc. www.binder-world.us
For further information on guidelines visit www.stability–test-chamber.com

Spherical Sensor in KBF-ICH above

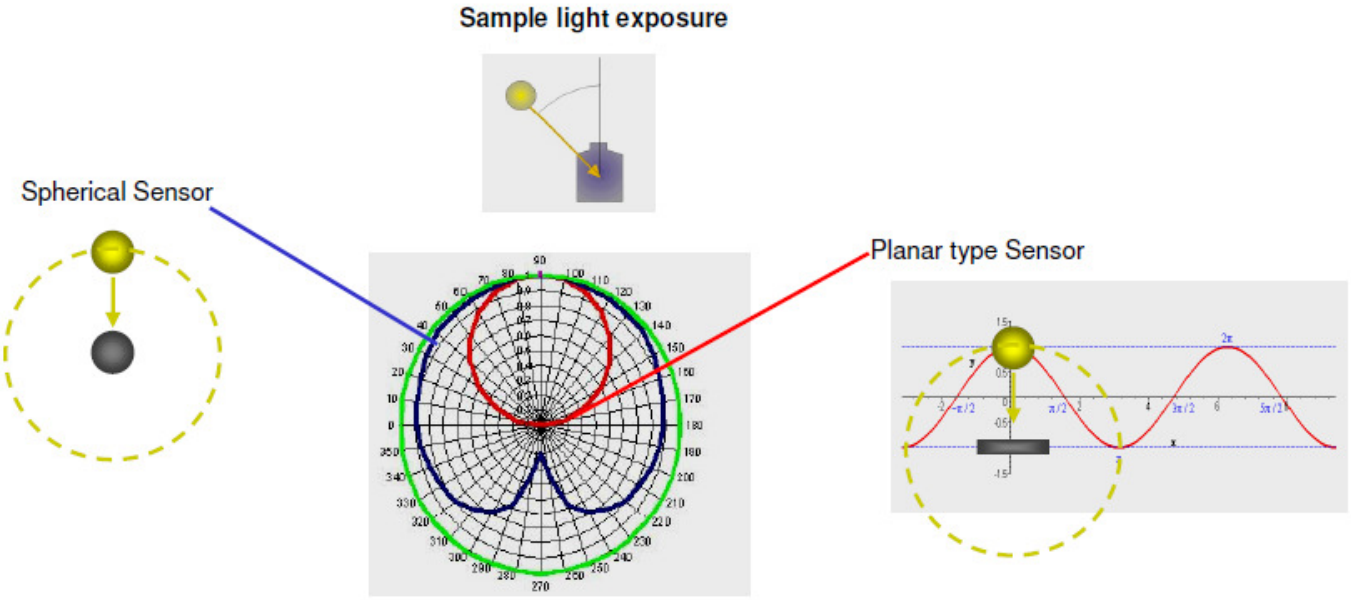
Planar type Sensor

**Binder UV and Vis light sensor**

**Atlas XenoCal radiometer**



**BINDER Inc.** ► 3500 Sunrise Highway / Ste D214 ► Great River, NY 11739 – Phone (631) 224 4340 – Fax (631) 224 4354 – Toll Free (866) 885 9794




Appendix: Top Left is Binder model KBF ICH conforming illumination available in 8.5 and 24.7 cu.ft. sizes. Please see lights in the door.
Middle left: Exclusive Binder light sensor included in above KBF ICH. Please note can be moved with in chamber.
Middle right: Planar type sensor not used in Binder. This type sensor used by many other manufacturers.
Bottom left: Graphic representation of Binder spherical sensor and it's ability to detect light in 3D.
Bottom middle: Graphical representation in blue of the spherical sensor and the planar sensor in red in volume.
Bottom right: The planar type sensor which values the exposure direction and does not coincide with the photochemical effect in a volume expanded system.



**BINDER Inc.** ► 3500 Sunrise Highway / Ste D214 ► Great River, NY 11739 – Phone (631) 224 4340 – Fax (631) 224 4354 – Toll Free (866) 885 9794