

Summation in SPF Calculations of the SPF-290AS™

Formulators face two interrelated issues when testing In-Vitro SPF values in their labs, especially when they are new to the task: The level of confidence in the equipment and the learning curve associated with sample preparation. The Optometries validation kit addresses both issues. It contains a calibration plate assembly and a set of standard formulations along with testing supplies.

The calibration plate includes non-volatile NIST traceable optical filters for testing photometric linearity and wavelength accuracy as well as one for In-Vivo correlation. Together with the 'Comprehensive Test' portion of WinSPF™ version 4.0, they provide a user-friendly tool for instrument validation.

The set of standard formulations allows the novice and experienced user alike to exercise their sample spreading skills and compare the results to known values of SPF 4 and SPF 15.



Impetus

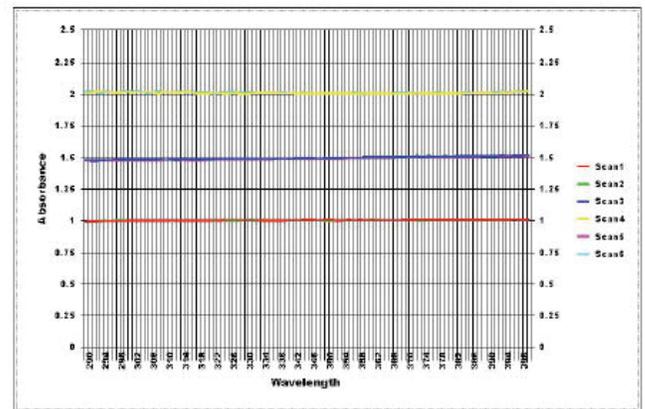
Many companies are engaged in ISO certification or other quality or calibration programs. The test plate and the "Comprehensive Test" module in the WinSPF™ software make it fast and simple to perform this self test and save the data electronically.

Cosmetic chemists have a daunting task with multiple ingredients, numerous variables, and a myriad of interactions. When they obtain unexpected results, they are sometimes inclined to suspect an

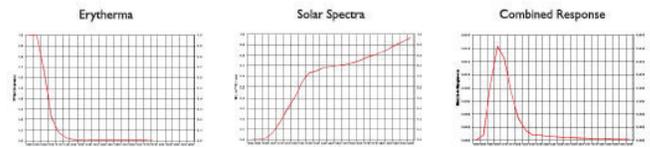
equipment malfunction. The validation kit was designed to eliminate any concerns the formulator has regarding analyzer calibration and to help address the challenge of uniform sample application.

The Test Plate

The test plate assembly includes three NIST traceable neutral density filters with absorbances of 1.0, 1.5 and 2.0.

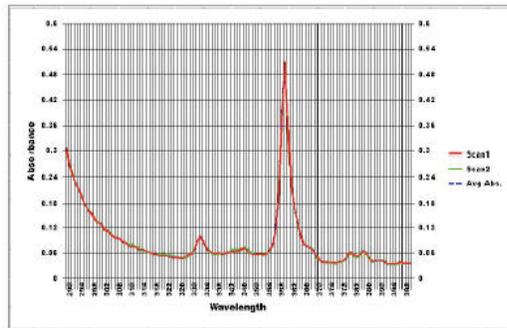


While the absorbance values are linear; the SPF values are not. The filters have SPF values of approximately 10, 33, and 100 respectively. The SPF values are approximate and non-linear because they are the result of multiplication by skin response (erythema) and solar spectra. (The SPF values will, however, be constant and repeatable.) The weighting factors combine to form a sharp peak at 306nm.



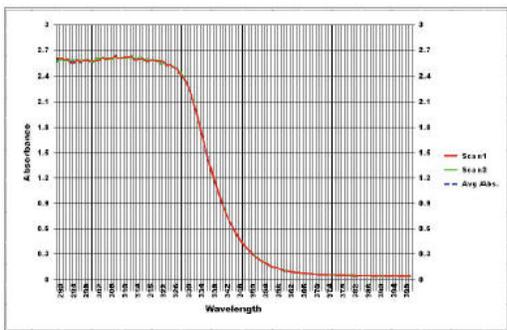
This most heavily weighted wavelength is the one at which the neutral density filters are tested (in absorbance) versus NIST standards. When the analyzer measures them and the values match their targets, the user is assured of absorbance accuracy and photometric linearity.

The assembly also includes a holmium oxide filter. This is a spectroscopic standard, also NIST traceable, used for testing wavelength accuracy. It has an absorption peak at 361nm.

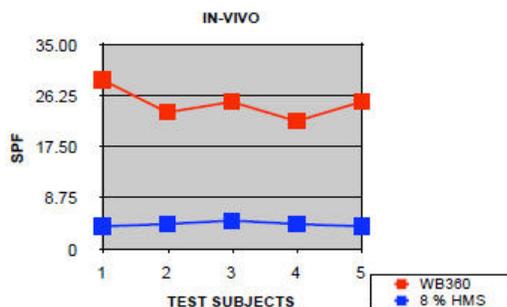


Photometric linearity and wavelength accuracy are the major criteria for a spectrophotometer, but the cosmetic chemist interested in SPF analysis could use something more.

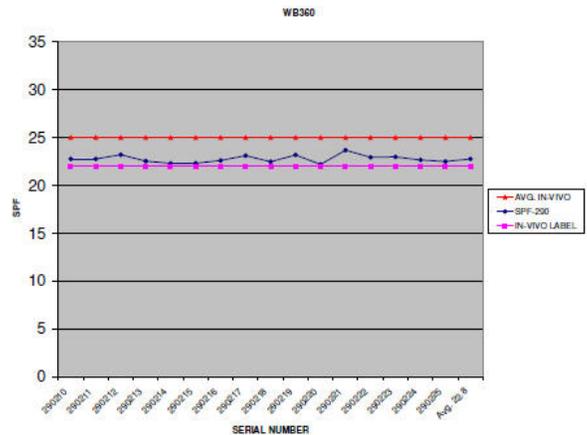
The WB-360, the last filter in the assembly, is a long pass color glass with an absorption curve which approximates that of a sunscreen formulation.



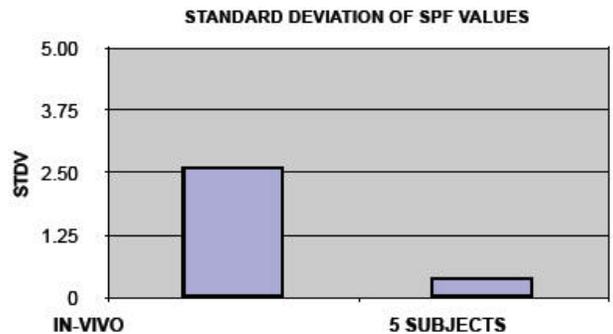
Unlike a formulation, it is not subject to the vagaries of sample preparation. It does not need to be formulated, weighed or measured. It does not need to be spread; its thickness doesn't change. It does not dry out or vary with time. As long as it is kept clean and undamaged, it has constant spectral properties. A set of this color glass was tested on an In-Vivo basis by an independent laboratory. The following graph shows the results along with the 8% homosalate control.



The WB-360 had an average SPF value of 25.0 and would be labeled SPF 22 due to the 95% confidence interval. The next graph shows In-Vitro results of WB-360 tested on sixteen recently built SPF-290AS™ analyzers showing excellent correlation.



The standard deviation of the In-Vivo test is shown below along side that of the sixteen analyzers. (For the SPF-290AS™. This is instrument-to-instrument variation. The standard deviation of multiple scans of WB-360 on one analyzer is virtually zero.)



To use the test plate, the user simply selects "Comprehensive Test" from the hpull down menu and clicks the "Begin" button in the window that opens. The user will be prompted to load the test plate and adjust the signal level, if necessary during the optimization routine. After that the X-Y stage and the software do all the work.

The stage positions the plate for a reference scan and then for each filter in turn. As each filter is measured (twice to ensure repeatability), the values are displayed in the space adjacent to their description in the "Comprehensive Test" window. The measurements are compared to their target values and the neighboring "light" turns green when they're found to be within specified tolerances.

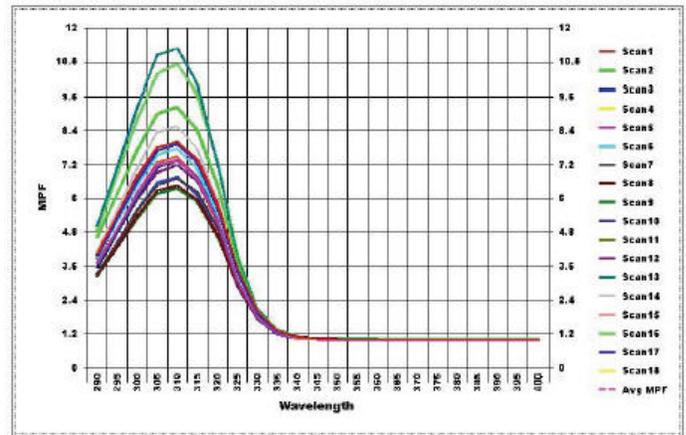
The user clicks the close button and the data is saved for later review and historical archive.

The Standard Formulations

The most difficult part of obtaining accurate results with any SPF analyzer is sample preparation. The correct thickness and uniform distribution of the formulation on the substrate is critical. We go into some detail on method and technique in the Help system of our WinSPF™ software under “Preparing Samples” and in item 6 of the tutorial section of the manual. In the end, though, it is practice that makes for good results.

The standard formulations are an 8% homosalte (USFDA) with an SPF of 4.47, and a P3/C202 (COLIPA) with a SPF of 15.5. (See graphs below).

With these readily available in the validation kit, formulators can check their technique whenever it's in question, when they're “rusty” from having not done it in a while or when technicians new to task are being trained. As one's method improves, results will converge on the known SPF values as stand deviation decreases.



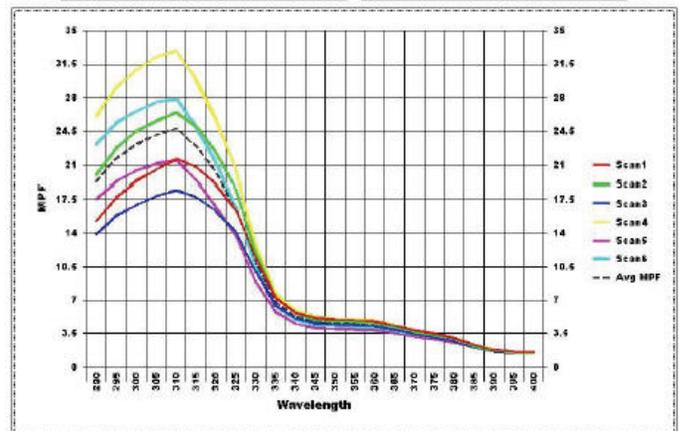
SPF-290 Graph Report

OPTOMETRICS

Measurement Information			
Date:	11/18/2005	Substrate:	Transpare
Time:	11:10:04 AM	Sample Prep:	2 ul/cm ²
Operator:	CM	Num. of Scans:	6
Wavelength Range:	290 to 400	Num. of Ref.:	2
Measurement Standard:	US FDA	Wavelength Step:	5 nm
Sample Name:	C202	Setup Filename:	test12.pw
Data Filename:	C202.spf	Solar Filename:	sp40r-00r.spf
Erythema Filename:	erythema.act		

Summary Results			
Solar Protection Factor:	15.73	STDV:	3.28
UVA/UVB ratio:	0.407		0.03
Boots Star Rating:	2		Moderate
Average UVA PF:	5.58		0.56
Erythema UVA PF:	8.58		0.50
Critical Wavelength:	376.4		0.42
Curve Area:	90.73		4.97

Measurement Parameters			
Parameter:	Value		
SPF STDV:	Classical		
Excluded Runs/Scans:			
Operating Mode:	Assey		
Assey STDV:	N/A		
Assey Slip Ref:	N/A		
Time-Based Mode:	N/A		
Time-Based Delay:	N/A		



SPF-290 Graph Report

OPTOMETRICS

Measurement Information			
Date:	02/28/2005	Substrate:	Transpare
Time:	7:27:13 AM	Sample Prep:	2 ul/cm ²
Operator:	CM	Number of Runs:	3
Wavelength Range:	290 to 400	Num. of Ref.:	2
Measurement Standard:	US FDA	Wavelength Step:	5 nm
Sample Name:	212.H50	Setup Filename:	212.H50.pw
Data Filename:	212.H50.spf	Solar Filename:	sp40r-00r.spf
Erythema Filename:	erythema.act		

Summary Results			
Solar Protection Factor:	4.47	STDV:	0.42
UVA/UVB ratio:	0.089		0.01
Boots Star Rating:	0		No Claim
Average UVA PF:	1.48		0.08
Erythema UVA PF:	1.70		0.06
Critical Wavelength:	328.4		0.37
Curve Area:	30.64		2.67

Measurement Parameters			
Parameter:	Value		
SPF STDV:	Classical		
Excluded Runs/Scans:			
Operating Mode:	Assey		
Assey STDV:	Using scans		
Assey Slip Ref:	True		
Time-Based Mode:	N/A		
Time-Based Delay:	N/A		

Conclusion

The validation kit provides a way for users to quickly and easily validate the accuracy and reproducibility of their SPF-290AS™ analyzer and to help monitor operator consistency in sample preparation demonstrating that they are obtaining reliable results.