

SUNJIN

Since 1978

Measurement of In-Vivo SPF test (SJ-MM-21)

- compliance with The International(COLIPA) SPF test method -

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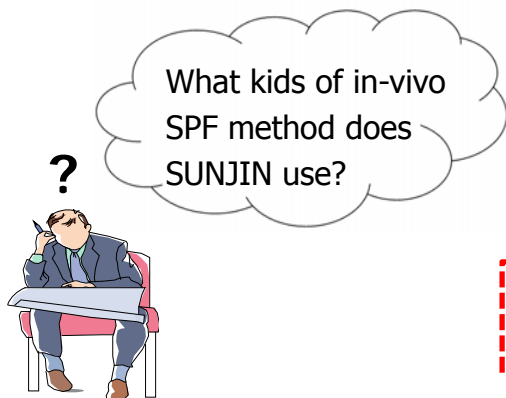
SUNJIN CHEMICAL CO.,LTD.

What kinds of in-vivo SPF test method does SUNJIN use?

Customer's Question ?

The developed countries have a in-vivo SPF test method apposite to the case of each Country.
SO customers request what kinds of in-vivo SPF test method does SUNJIN use.

Customer's Question




The contract manufacturer LABORATORIOS MAGRIÑA is very interested in your formulations. As I was explaining you during this last days, they would like to reach 40SPF but with the formulation SJ-1003 they only obtain a 30 SPF. This new formulation it could be the solution for 8 customers, 8 final brands so this is the reason I contact you again, because of this potential consumption.

Could you please let CESTISA know if you could send the method, the results of the in-vivo test to CESTISA? Because our customer Magriña is using a different method.

Why does customer Question?

The developed countries have a in-vivo test method apposite to the case of each Country.
ex) JCIA, CTFA, CTFA/SA, FDA, CHINA, KFDA(KOREA)

SUNJIN complies with International(COLIPA) in-vivo SPF test method.



International(COLIPA) method vs SUNJIN method

SUNJIN complies with International(COLIPA) in-vivo SPF test method in all aspects (equipment, Procedure, Assessment, .. etc) except number of subjects

		International standard (COLIPA, JCIA, CTFA, CTFA/SA)	SUNJIN
Equipment	Ultraviolet light source	Filtered Xe arc. lamp	Filtered Xe arc. lamp
Panel selection	Number of subjects	10 ~ 20	3
	Skin phototype	Fitzpatrick 1,2,3 or ITA value > 28°	Fitzpatrick 1,2,3
Procedure	Test area	back (between the scapula and the waist)	back (between the scapula and the waist)
	Applying area	30~60cm ²	30cm ²
	Amount	2.0mg/cm ² ± 0.05mg/cm ²	2.0mg/cm ² ± 0.05mg/cm ²
	Drying time	15~30 min	15~30min
	Incremental progression of UV dose	SPF : x1.15(expected SPF ≥ 25), x1.25(expected SPF < 25)	SPF : x1.15(expected SPF ≥ 25), x1.25(expected SPF < 25)
assessment	Time of assessment	20 ± 4hr	20 ± 4hr

SUNJIN's in-vivo SPF test method



1. Equipment

SUNJIN uses SPF Testing 601-300W Multiport UV Solar Simulator and photometer/Radiometer manufactured by SOLAR LIGHT which complies with international standards(COLIPA).

1. SPF Testing 601-300W Multiport

UV Solar Simulator >



< Ultraviolet light source >

1. Continuous, stable, uniform Filtered Xe arc. Lamp
2. UVA irradiance
 - UVA II (320~340nm) : equal or exceed 20% of the total UV
 - UVA I (340~400nm) : equal or exceed 60% of the total UV
3. Total irradiance : under 160mW/cm²
4. Incremental progression of UV dose
 - SPF : x1.15(expected SPF ≥ 25), x1.25(expected SPF < 25)

2. Photometer/Radiometer(PMA2100)



< Ultraviolet light source check >

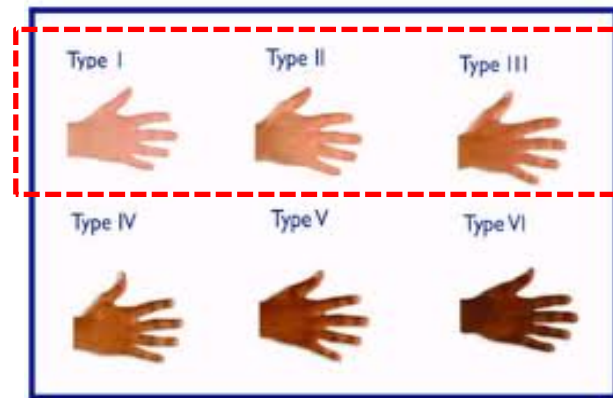
1. It checks whether Ultraviolet light source is Continuous and stable.
2. It is used when controlling Ultraviolet light source of every port

2. Panel selection

The skin phototype of panel included in the SPF test shall be phototypes I, II, or III according to Fitzpatrick

1. skin phototypes of Fitzpatrick

- Type 1 : always burns easily (never tans)
- Type 2 : always burns easily (tans minimally)
- Type 3 : burns moderately (tans gradually)
- Type 4 : burns minimally (always tans well)
- Type 5 : rarely burns (tans profusely)
- Type 6 : never burns (deeply pigmented)



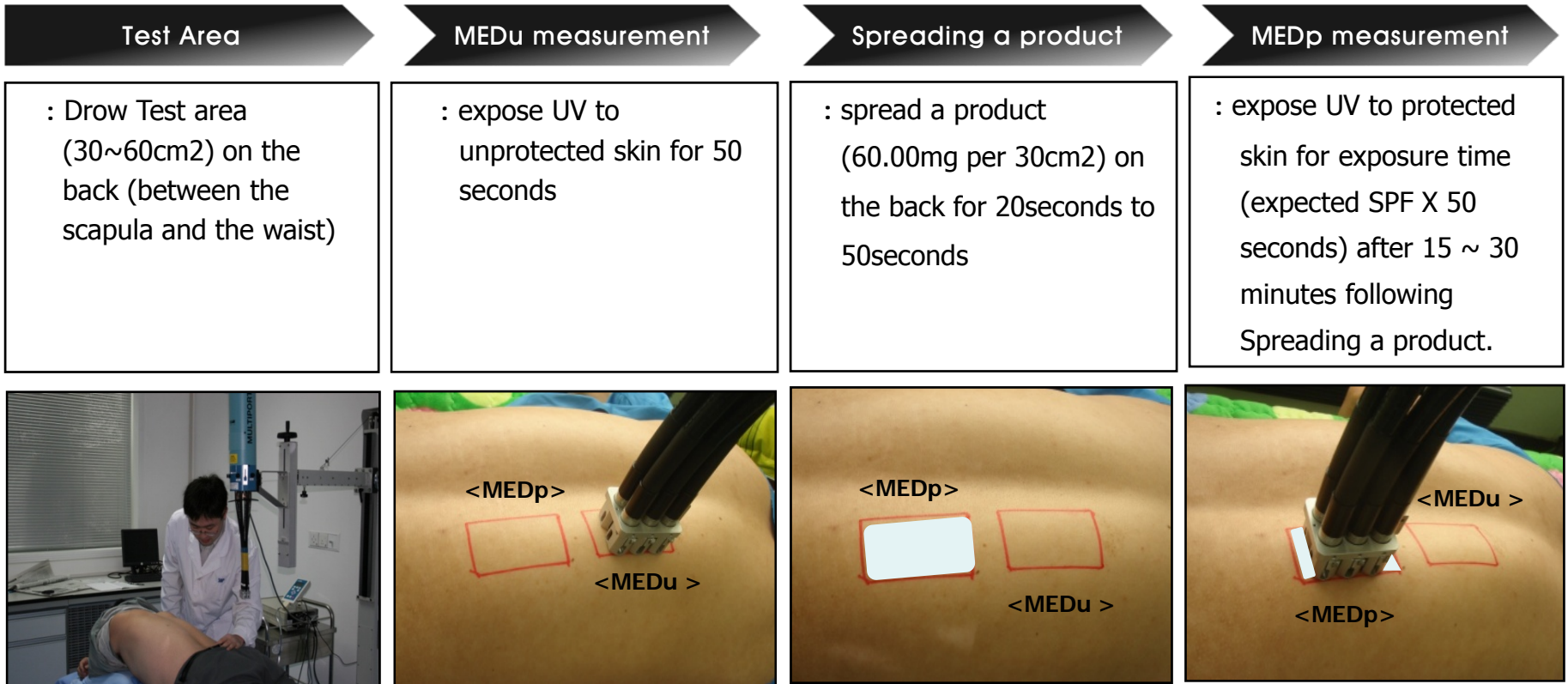
SUNJIN uses the skin phototypes I, II, or III according to Fitzpatrick.

2. Number of panel : **3 valid results / test**

< Difference with international SPF test method - number of subjects : 10 valid results / test >

3. Procedure

SUNJIN follows procedure as below


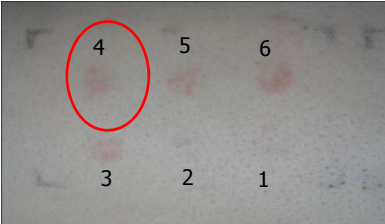


4. Assessment

The MED shall be assessed when the erythral response is optimal, i.e. 20 ± 4 hours after UV exposure (between 16 and 24 hours).

For example

<MED_u – MED of Unprotected skin> <MED_p – MED of protected skin >

light-intensity of each Port

1 : 1.04 med/min	2 : 1.20 med/min
3 : 1.39 med/min	4 : 1.60 med/min
5 : 1.84 med/min	6 : 2.11 med/min

MED_u
 : 1.60 med/min * 50sec * 21mj/(cm² * med)
 * 1min/60sec = 28mj/cm²

MED_p
 : 1.60 med/min * 50sec * 21mj/(cm² * med)
 * 1min/60sec * 50spf = 1400mj/cm² * spf

Calculating Result : MED_p / MED_u
 : 1400 mj/cm² * spf / 28mj/cm²
 = **50 SPF**

< assessment method >

1. The result is measured by 2 experts.
2. Number of subjects : **3 valid results** / test
3. Sun protection factor : SPF = MED_p (protected skin) / MED_u (unprotected skin)
4. the final result : $\Sigma \text{SPF} / 3$

Ex) 50, 53, 48 → 151 / 3 = 50.3