

## TiO<sub>2</sub>-free coatings:

Comparing the degree of whiteness, achieved with titanium dioxide-free immediate release coatings

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# TiO<sub>2</sub> free coatings: Introduction

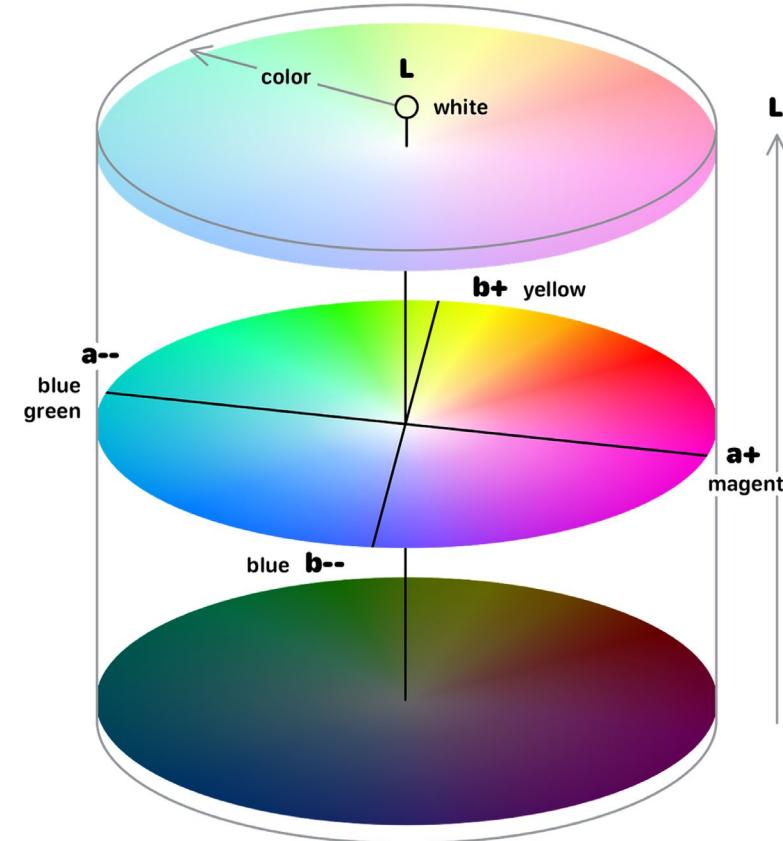


In the pharmaceutical industry, the standard white pigment is **titanium dioxide (TiO<sub>2</sub>)**, and the standard opacifier is talc.

In an opinion letter of EFSA (European Food Safety Authority), published May 2021, titanium dioxide is **no longer considered safe due to uncertainty of genotoxicity due to nanoparticles contained**. Subsequently, a food ban was announced in January 2022.

Even though the pharmaceutical industry is currently not affected, pharmaceutical companies have started to reformulate their drug products to be prepared for a potential ban.

# TiO<sub>2</sub> free coatings: The Cie-Lab System



L scale: 0 to 100 (brightness)  
a scale: -170 to +100 (blue green to magenta)  
b scale: -100 to +150 (blue to yellow)

- „ideal black“: L 0; a 0; b 0
- „ideal white“: L 100; a 0; b 0

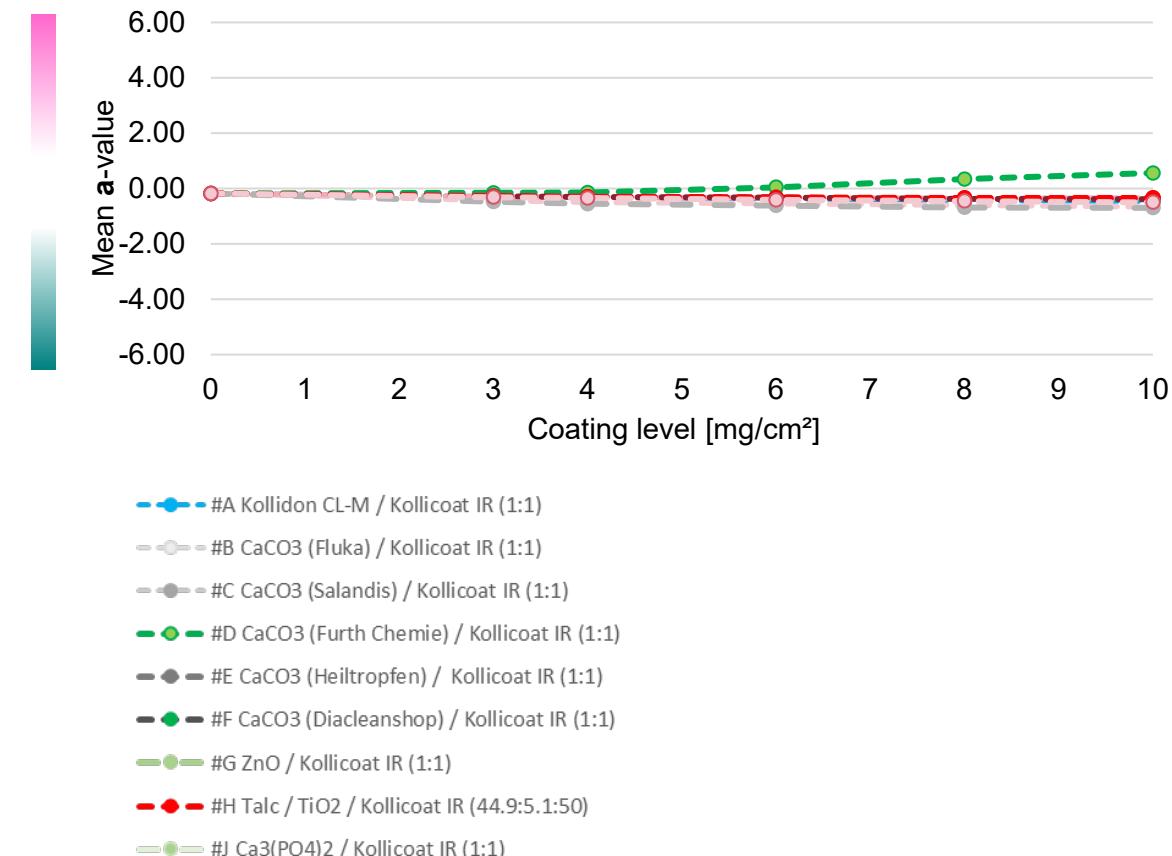
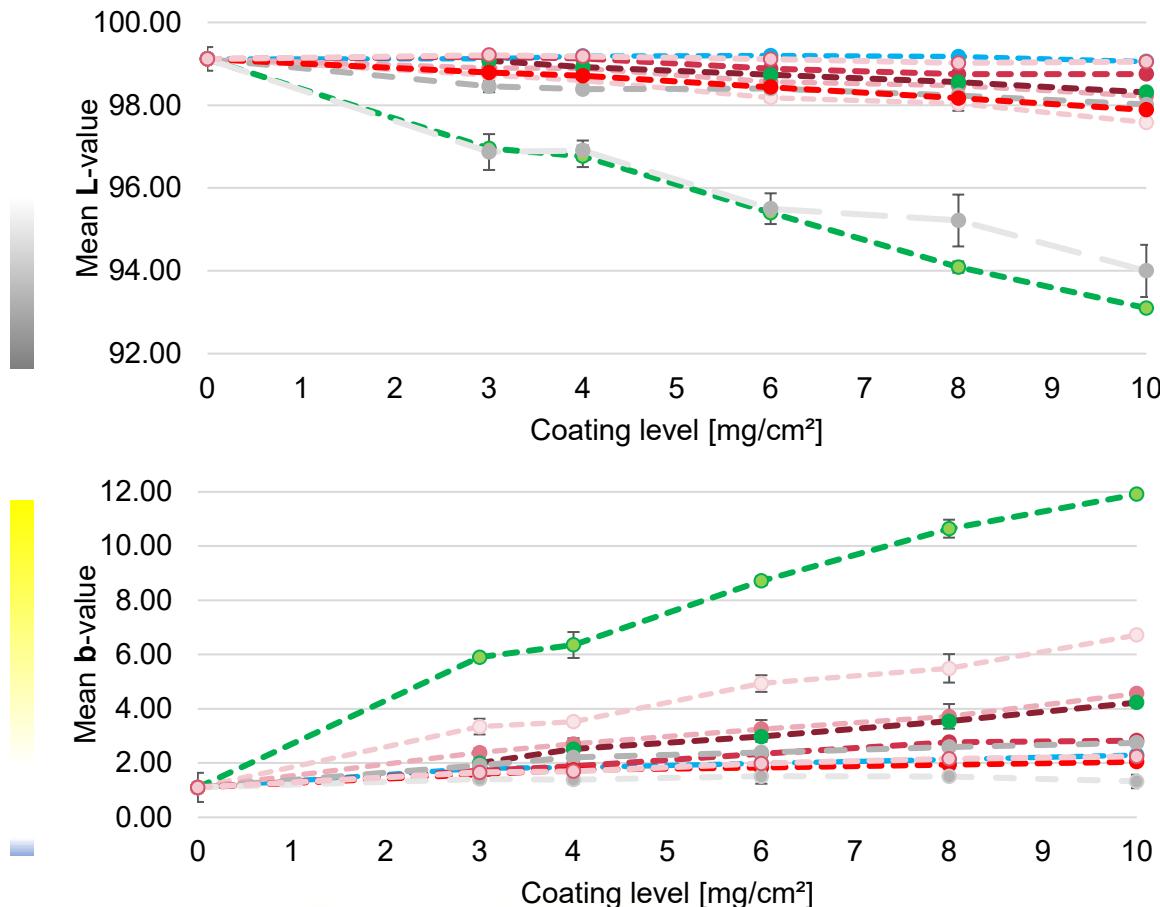
**Delta E** (dE;  $\Delta E$ ) represents the distance between two colors in the CIE-Lab system. It is calculated from the coordinates of two colour locations. With the  $\Delta E$ -value, differences between two colors (that are perceived by human eye), can be assigned to numbers.

$$\Delta E = \sqrt{(L_0 - L_1)^2 + (a_0 - a_1)^2 + (b_0 - b_1)^2}$$

# TiO<sub>2</sub> free coatings: Degree of Whiteness

Coating level [mg/cm <sup>2</sup> ]	Kollidon® CL-M/ Kollicoat® IR (1:1)	CaCO <sub>3</sub> (Fluka)/ Kollicoat® IR (1:1)	CaCO <sub>3</sub> (Salandis)/ Kollicoat® IR (1:1)	CaCO <sub>3</sub> (Furth)/ Kollicoat® IR (1:1)	CaCO <sub>3</sub> (Heiltropfen)/ Kollicoat® IR (1:1)	CaCO <sub>3</sub> (Diacleanshop)/ Kollicoat® IR (1:1)	ZnO/ Kollicoat® IR (1:1)	TiO <sub>2</sub> /Talc/ Kollicoat® IR (5.1/44.9/50)	Ca <sub>3</sub> (PO <sub>4</sub> ) <sub>2</sub> / Kollicoat® IR (1:1)	Kollicoat® IR
10	ΔE <sub>idial white</sub> : 2.5	ΔE <sub>idial white</sub> : 7.2	ΔE <sub>idial white</sub> : 4.9	ΔE <sub>idial white</sub> : 13.8	ΔE <sub>idial white</sub> : 3.1	ΔE <sub>idial white</sub> : 4.6	ΔE <sub>idial white</sub> : 3.5	ΔE <sub>idial white</sub> : 3.0	ΔE <sub>idial white</sub> : 6.2	ΔE <sub>idial white</sub> : 2.5
8	ΔE <sub>idial white</sub> : 2.3	ΔE <sub>idial white</sub> : 5.9	ΔE <sub>idial white</sub> : 4.0	ΔE <sub>idial white</sub> : 12.2	ΔE <sub>idial white</sub> : 3.1	ΔE <sub>idial white</sub> : 3.8	ΔE <sub>idial white</sub> : 3.2	ΔE <sub>idial white</sub> : 2.7	ΔE <sub>idial white</sub> : 5.0	ΔE <sub>idial white</sub> : 2.4
6	ΔE <sub>idial white</sub> : 2.2	ΔE <sub>idial white</sub> : 5.3	ΔE <sub>idial white</sub> : 3.6	ΔE <sub>idial white</sub> : 9.9	ΔE <sub>idial white</sub> : 2.6	ΔE <sub>idial white</sub> : 3.2	ΔE <sub>idial white</sub> : 2.9	ΔE <sub>idial white</sub> : 2.4	ΔE <sub>idial white</sub> : 4.8	ΔE <sub>idial white</sub> : 2.2
4	ΔE <sub>idial white</sub> : 2.0	ΔE <sub>idial white</sub> : 3.8	ΔE <sub>idial white</sub> : 2.9	ΔE <sub>idial white</sub> : 7.1	ΔE <sub>idial white</sub> : 2.1	ΔE <sub>idial white</sub> : 2.8	ΔE <sub>idial white</sub> : 2.8	ΔE <sub>idial white</sub> : 2.2	ΔE <sub>idial white</sub> : 3.4	ΔE <sub>idial white</sub> : 1.9
3	ΔE <sub>idial white</sub> : 2.0	ΔE <sub>idial white</sub> : 3.6	ΔE <sub>idial white</sub> : 2.6	ΔE <sub>idial white</sub> : 6.6	ΔE <sub>idial white</sub> : 2.0	ΔE <sub>idial white</sub> : 2.2	ΔE <sub>idial white</sub> : 2.5	ΔE <sub>idial white</sub> : 2.0	ΔE <sub>idial white</sub> : 3.4	ΔE <sub>idial white</sub> : 1.9
0	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4	ΔE <sub>idial white</sub> : 1.4

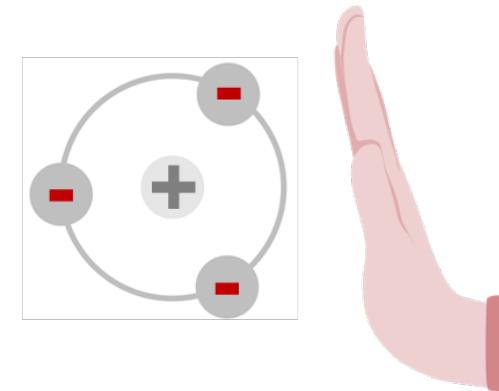
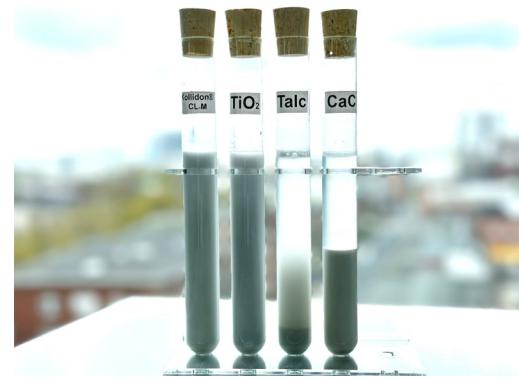
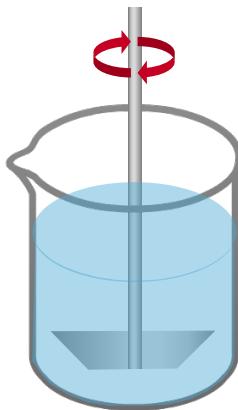
# TiO<sub>2</sub> free coatings: L, a and b Values by Coating, Applied



INTEGRATING  
Delivery Science  
ACROSS DISCIPLINES

# TiO<sub>2</sub> free coatings: Application Benefits of Kollidon® CL-M in Coating Formulations

- Simplified preparation of the coating formulation, as **no high shear** mixer for particle disaggregation is required!
- Due to the low specific density of Kollidon® CL-M, **sedimentation in the preparation vessel and tubing is low** and leads to a **high process reliability**.
- Kollidon® CL-M **doesn't form salts with (functional) polymers or active pharmaceutical ingredients (API)**.



Kollidon® CL-M meets the requirements of the current "Crosppovidone" monographs Type B of **Ph. Eur.**, **USP-NF** and **JP** (English version).