

TiO₂-free coatings:

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

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TiO₂ free coatings:

Introduction



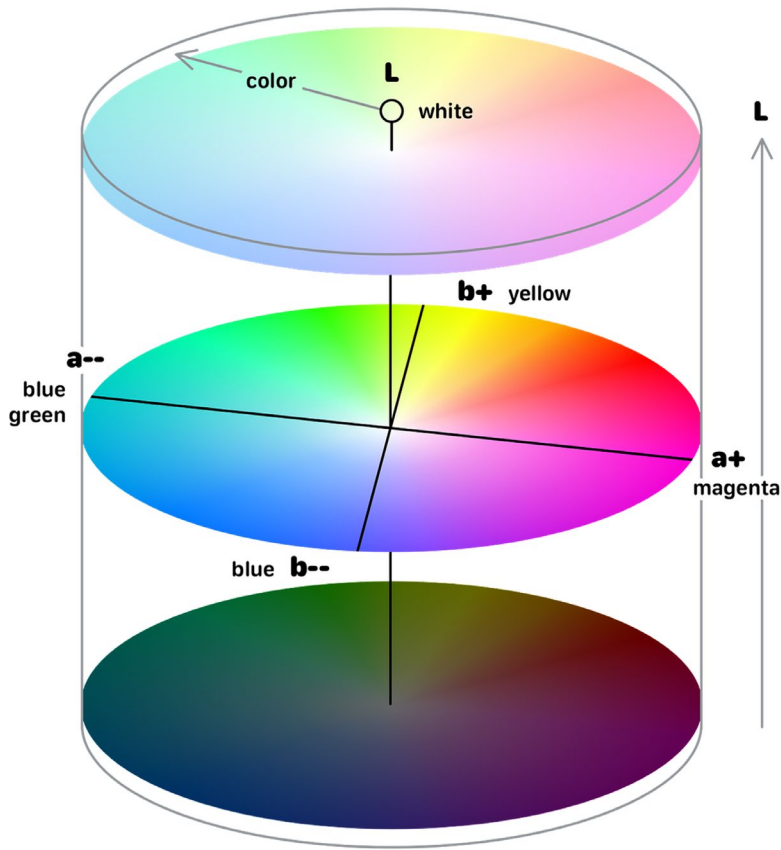
In the pharmaceutical industry, the standard white pigment is **titanium dioxide (TiO₂)**, and the standard opacifier is talc.

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.



TiO₂ 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

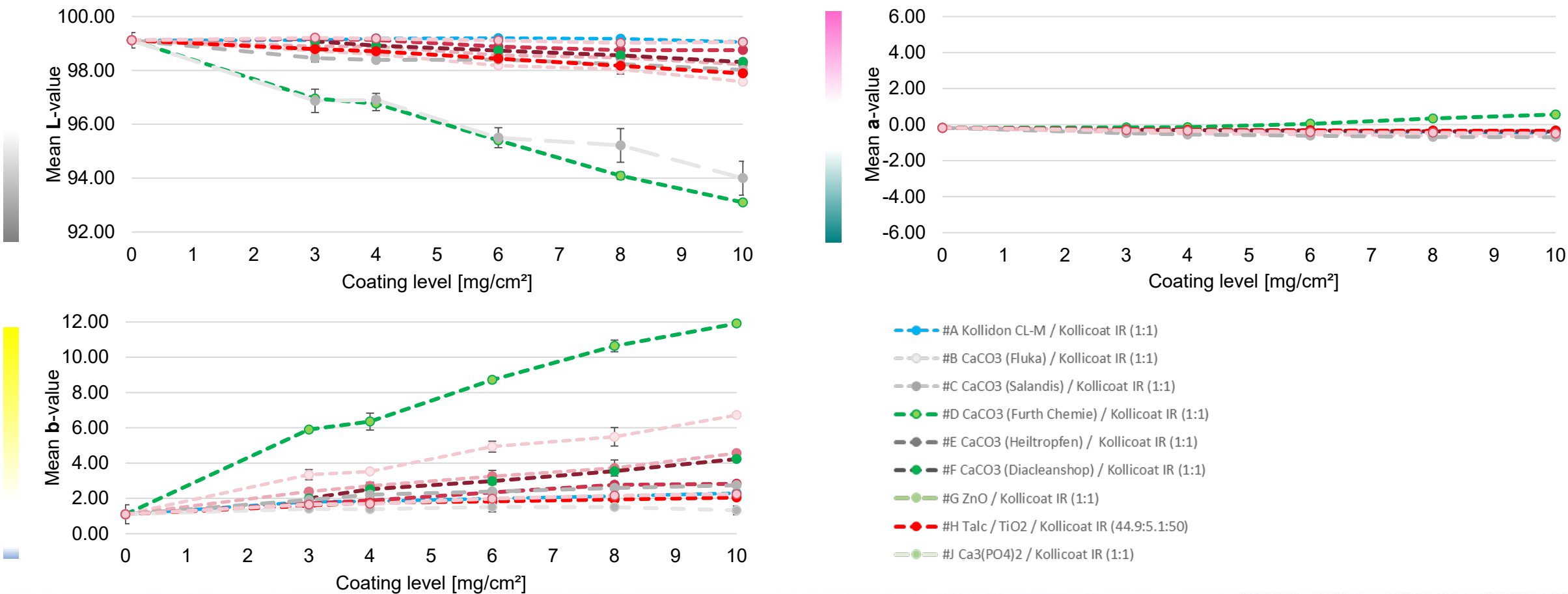
Delta E (dE; ΔE) represents the distance between two colors in the CIE-Lab system. It is calculated from the coordinates of two colour locations. With the ΔE -value, differences between two colors (that are perceived by human eye), can be assigned to numbers.

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

TiO₂ free coatings: Degree of Whiteness

[illegible]

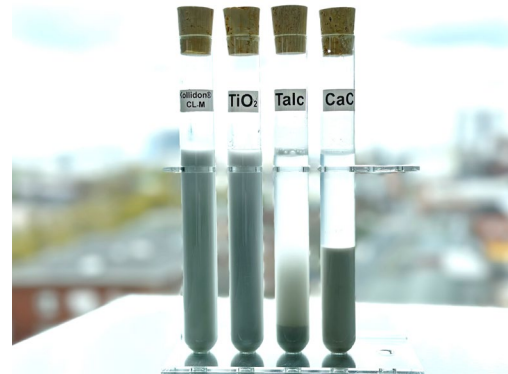
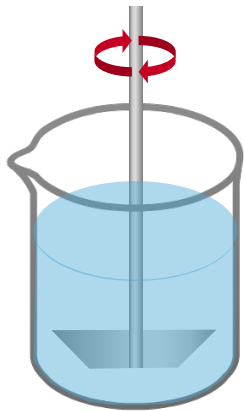
TiO₂ free coatings: L, a and b Values by Coating, Applied



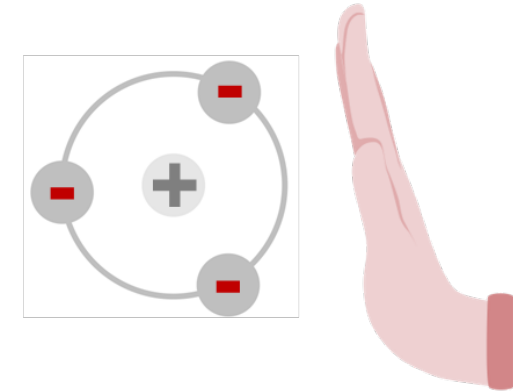
TiO₂ free coatings:

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)**.



* Photo taken 30 minutes after redispersion



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

