

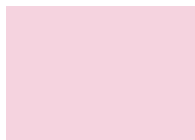


Kollicoat® IR Coating Systems

 **BASF**

The Chemical Company

Pharma Ingredients & Services.
Welcome to more opportunities.



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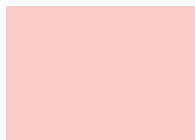
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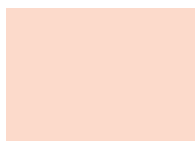
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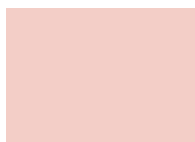
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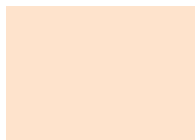
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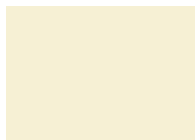
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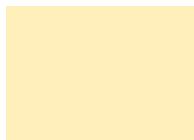
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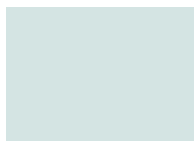
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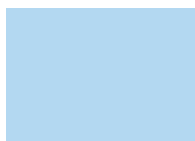
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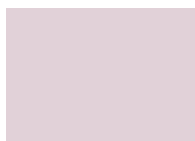
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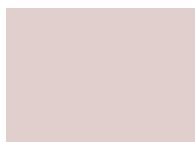
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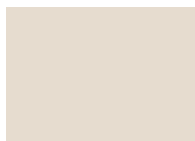
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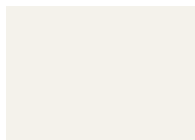
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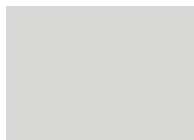
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Grey
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Kollicoat IR Coating Systems are ready-to-use colored coating materials based on Kollicoat IR (polyvinyl alcohol polyethylene glycol graft copolymer). This innovative product line consists of five individual colored components, completed by a black and a white coating material:

[Kollicoat IR Brilliant Blue](#)

[Kollicoat IR Carmine](#)

[Kollicoat IR Sunset Yellow](#)

[Kollicoat IR Red](#)

[Kollicoat IR Yellow](#)

[Kollicoat IR Black](#)

[Kollicoat IR White II](#)

From the seven basic components it is possible to obtain a wide variety of shades of colored coatings simply by combining different numbers and concentrations of these individual components.

Approved pigments in Kollicoat IR Coating Systems

Pigment	Sunset Yellow	Carmine	Brilliant Blue	Titanium dioxide	Iron oxides
E-numbers	E 110	E 120	E 133	E 171	E 172
CAS-no	2783-94-0	1390-65-4	3844-45-9	13463-67-7; 1317-70-0	Yellow 51274-00-1, 20344-49-4; Red 1309-37-1; Black 1317-61-9, 12227-89-3
Pharmacopoeial monographs	–	JPE	–	Ph.Eur., USP, JP	USP (Ferric oxide), JPE
Limits					
Medicinal products (EU)	q.s.	q.s.	q.s.	q.s.	q.s.
Medicinal products (U.S.)	q.s.	q.s.	q.s.	q.s.	≤ 5 mg/d ³
Medicinal products (Japan)	≤ 0.1% [w/w] ¹	≤ 1.8 mg/d ²	≤ 1% [w/w] ¹	≤ 384 mg/d ²	Red ≤ 95.4 mg/d ² Yellow ≤ 5.67 mg/d ² Black ≤ 1.539 mg/d ²

¹ Not more than 0.1% by weight of color (lake or dye) can be used in a dosage form (MHLW's BIRYO limit on trace amounts).

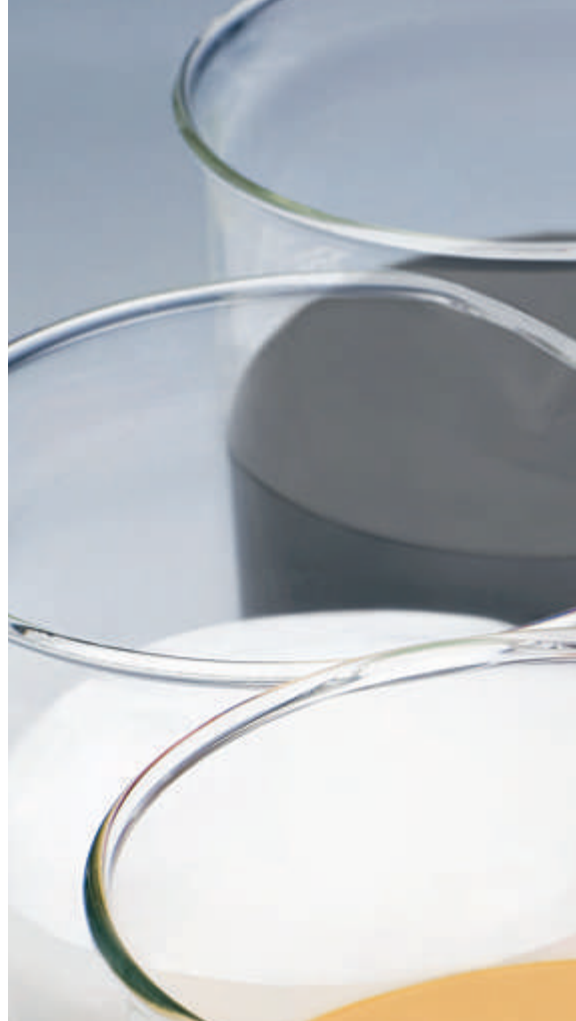
² Limit acc. to the dictionary of Pharmaceutical Excipients (Japan)

³ May be safely used to color ingested or topically applied drugs. Generally subject to the restrictions that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron per day (Code of Federal Regulations Title 21 Food and Drugs).

Approved polymer in Kollicoat IR Coating Systems

Kollicoat IR (film forming polymer in Kollicoat IR Coating Systems) was approved as coating material in medicinal products in the U.S., the EU, in Japan and in several other countries all over the world.

A draft Ph.Eur. monograph entitled “Macrogol Poly(vinylalcohol) Grafted Copolymer” was published in PharmEuropa 20/3, 2008. A draft USP/NF monograph entitled “Ethylene Glycol and Vinyl Alcohol Graft Copolymer” was published in Pharmacopoeial Forum 35(2).



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