



Pharma Ingredients & Services. Welcome to more opportunities.

Custom Synthesis I Excipients I Active ingredients

	I		I	1	I
Pink 248218228	Pink 233179202	Pink 223157187	Pink 206125161	Pink 189100136	Pink 176084118
Pink 255215209	Pink 231174178	Pink 239152151	Pink 221153159	Pink 200125131	Pink 165074104
Red 251223210	Red 240189173	Red 229170153	Red 196122102	Red 177101081	Red 166087074
Red 246214208	Red 212143123	Red 183106095	Red 162082084	Red 122082084	Red 113084078
Red 231177170	Red 218155148	Red 199126117	Red 183102108	Red 184076078	Red 150078080
Orange 255225206	Orange 255186152	Orange 255171127	Orange 250144089	Orange 229121069	Orange 179108070

		1	I	I	I
Orange 255217197	Orange 255162111	Orange 255148098	Orange 255128082	Orange 255113065	Orange 250101060
Yellow 253242219	Yellow 255226184	Yellow 251196129	Yellow 238179108	Yellow 219158083	Yellow 230168093
Green 151177176	Green 129157157	Green 096129129	Green 026116112	Green 062083085	Green 069086088
Green 186233227	Green 124204199	Green 096189184	Green 047164159	Green 007140136	Green 076109111
Green 197215212	Green 190217218	Green 139181185	Green 114160166	Green 083128135	Green 073109115
Blue 150226236	Blue 121190203	Blue 091172188	Blue 056144162	Blue 043118137	Blue 068096100

	I	1	I	I	I
Blue 187220231	Blue 132185210	Blue 107165195	Blue 070134170	Blue 000110150	Blue 041093109
Blue 047200226	Blue 000184217	Blue 000137181	Blue 055108145	Blue 053093128	Blue 054083113
Purple 232218224	Purple 197182196	Purple 178161179	Purple 148130150	Purple 122105125	Purple 096081096
Brown 232216212	Brown 200178176	Brown 182157156	Brown 153127125	Brown 131104101	Brown 112087079
Brown 233230219	Brown 200198188	Brown 180180169	Brown 153153141	Brown 128128117	Brown 106105094
White 249247240	Grey 222223222	Grey 179185190	Grey 158165172	Grey 127135143	Black 077081087

### Create your own colors.

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 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

These seven base colors can be combined to create hundreds of different shades. In addition, faster and more straightforward production processes enable energy costs and carbon emissions to be reduced.

### Approved polymer in Kollicoat IR Coating Systems.

Kollicoat IR has been approved as a coating material for drug products in the US, the EU, in Japan and in several other countries all over the world.

Kollicoat IR monographs are published in Ph.Eur. entitled "Macrogol Poly(vinyl alcohol) Grafted Copolymer" and USP entitled "Ethylene Glycol and Vinyl Alcohol Graft Copolymer".

## **DMF for Kollicoat IR Coating Systems.**

A Type IV US Drug Master File "Kollicoat IR Coating Systems" has been filed with the FDA (DMF #23187).

### Approved pigments in Kollicoat IR Coating Systems.

Pigment	Sunset Yellow	Carmine	Brilliant Blue	Titanium Dioxide	ide Iron Oxides	
CAS-No	2783-94-0	1390-65-4	3844-45-9	13463-67-7;	Yellow	51274-00-1,
				1317-70-0		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						
Drug products (EU)	q.s.	q.s.	q.s.	q.s.		q.s.
Drug products (US)	q.s.	q.s.	q.s.	q.s.		≤5 mg/d³
Drug products (Japan)	≤0.1 % [w/w]¹	≤1.8 mg/d²	≤1 % [w/w]¹	≤384 mg/d²	Red	≤95.4 mg/d²
					Yellow	≤5.67 mg/d²
					Black	≤1.539 mg/d²

<sup>&</sup>lt;sup>1</sup> 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).

<sup>&</sup>lt;sup>2</sup> Limit acc. to the dictionary of Pharmaceutical Excipients (Japan).

<sup>&</sup>lt;sup>3</sup> May be safely used to color ingested or topically applied drug products. Generally subject to the restrictions that if the color additive is used in drug products 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).

- Easy color creation based on only seven colors
- Higher production efficiency and reduced complexity
- Fast re-dispersion and robust product handling
- Immediate availability of color samples

# What Kollicoat IR Coating Systems can do for you.

Kollicoat IR Coating Systems are robust and rapidly dispersible and facilitate the creation of high-quality, instantly-recognizable coatings in a wide range of shades. Even better, creating colored coatings on-site is quick and easy - and means you depend less on suppliers.



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