

New monographs for Kollicoat[®] MAE 100 P and Kollicoat[®] SR 30 D in the European Pharmacopoeia

The revised monograph “Methacrylic Acid – Ethyl Acrylate Copolymer (1:1)” was published in supplement 5.7 of the European Pharmacopoeia and has become effective in April 2007. This monograph now includes both types of the polymer, the “acid form, Type A” and the “partially neutralized form, Type B”. Type B is also known as BASF’s **Kollicoat[®] MAE 100 P**. The product is manufactured in a spray-drying process of Kollicoat[®] MAE 30 DP and sodium hydroxide (Ph.Eur, USP, JP). The powder can easily be re-dispersed in aqueous solutions. An addition of sodium hydroxide prior to re-dispersion is not necessary. The Kollicoat[®] grades are used as enteric coating for solid oral dosage forms.

A new monograph for BASF’s **Kollicoat[®] SR 30 D** with the title “Poly(Vinyl Acetate) Dispersion 30 Per Cent” was published in supplement 5.8 of the European Pharmacopoeia and will become effective in July 2007. **Kollicoat[®] SR 30 D** is an aqueous dispersion of polyvinyl acetate stabilized with povidone and sodium lauryl sulfate. The product is recommended for pH-neutral sustained release applications or for taste masking.

The following table gives an overview of the monographs of BASF’s Kollicoat[®] grades:

Product	Application	Ph.Eur	USP/NF	JPE
Kollicoat [®] MAE 30 DP	Enteric coating	Methacrylic Acid - Ethyl Acrylate Copolymer 1:1 Dispersion 30 Per Cent	Methacrylic Copolymer Dispersion	Methacrylic Acid Copolymer LD
Kollicoat [®] MAE 100 P		Ph.Eur 5.7 Methacrylic Acid – Ethyl Acrylate Copolymer 1:1 (Type B)		
Kollicoat [®] SR 30 D	Sustained release applications	Ph.Eur 5.8 Poly (Vinyl Acetate) Dispersion 30 Per Cent		
Kollicoat [®] IR	Instant release coating	The monograph for Kollicoat [®] IR (“Polyethylene glycol polyvinyl alcohol grafted copolymer”) has been applied for.		
Kollicoat [®] IR White				
Kollicoat [®] Protect				