



The Chemical Company

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Product News

Kollicoat IR: Draft monograph for the European Pharmacopoeia

For the first time, a draft monograph for the European Pharmacopoeia regarding the excipient Kollicoat® IR by BASF has been published. This draft monograph appeared under the title “Macrogol – polyvinyl alcohol – graft copolymer” (#2523) in the 20/3 edition of *Pharmeuropa (The European Pharmacopoeia Forum)* of July 2008.

Kollicoat IR is a water-soluble polymer that is used as a film former for the production of instant-release tablet coatings. This way, active ingredients can be released without delay shortly after the tablets are taken. Using Kollicoat IR it is possible to produce high-quality, visually appealing tablets of great mechanical stability without requiring plasticizers. Moreover, the polymer helps manufacturers make the coating process more efficient and economical.

Solid oral dosage forms containing Kollicoat IR have been approved in Germany since 2005 and in France, Great Britain, Spain and Portugal since May 2007. In April 2008, the US Food and Drug Administration (FDA) licensed a drug with a Kollicoat IR coating for the first time (ANDA # 75-661). Kollicoat IR has been registered in Japan since August 2007.

Kollicoat IR is manufactured by BASF in Germany according to cGMP guidelines. The polymer is marketed worldwide under the brand name Kollicoat IR and is also contained in the products Kollicoat IR White (ready-to-use preparation for white film coatings) and Kollicoat Protect (instant-release coatings for moisture protection).

More detailed information is available from pharma-ingredients@basf.com