

Influence of partially pregelatinized starches on the dissolution of drugs with varying solubility from capsule formulations

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Purpose.

To compare the effect of partially pregelatinized starches (LYCATAB®C and Starch®1500) on the dissolution rate of highly soluble, not very soluble and poorly soluble drugs from capsule formulations.

Methods.

Capsule formulations containing a highly soluble drug (Propranolol HCl), not very soluble drug (Acetaminophen) and a poorly soluble drug (Ibuprofen) were prepared on an Instron capsule-filling simulator, using either LYCATAB®C or Starch®1500 as the filler. A rotating basket dissolution apparatus (EP) was used to study the drug dissolution from these capsule formulations over a pH range of 1.3 – 7.2. Aliquots of the dissolution media were sampled periodically and the rate of drug dissolution was analyzed by measuring the UV absorbance at appropriate wavelengths.

Results.

At pH 1.3, 4.7 and 5.8, the formulations with LYCATAB®C exhibited 90-100% dissolution of the highly soluble Propranolol HCl within 10 min compared to 40-50% dissolution with Starch®1500 under similar conditions. Similar results were obtained for the dissolution of the not very soluble Acetaminophen. At pH 1.3 and 7.2, no significant differences were observed in the dissolution rate of the poorly soluble Ibuprofen from formulations containing either LYCATAB®1500 under similar conditions. Similar results were obtained for the dissolution of the not very soluble Acetaminophen. At pH 1.3 and 7.2, no significant differences were observed in the dissolution rate of the poorly soluble Ibuprofen from formulations containing either LYCATAB C or Starch®1500. Rather, the rate of Ibuprofen dissolution was influenced largely by the pH of the dissolution medium.

Conclusion.

Compared to Starch®1500, LYCATAB® C exhibits a significantly higher dissolution rate for the highly soluble drug propranolol HCl and the not very soluble drug acetaminophen over a wide pH range. However, no significant difference is observed in the dissolution of the poorly soluble drug Ibuprofen, with LYCATAB®C or Starch®1500.