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The role of preformulation in the choice of rectal formulation: Case study of Ceftriaxone

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Ceftriaxone is a wide spectrum antibiotique currently existing as injectable powder for extemporaneous reconstitution before intreveinous or intramuscular administration. The aim of our project was to formulate rectal pediatric forms. Ceftriaxone belongs to Biopharmaceutical classification System (BCS) classe 3, meaning that it is well soluble, but weakly permeable. Furthermore, it is described as sensitive to degradation in several conditions. A large preformulation study was therefore conducted to define its processability and identify conditions leading to its degradation. The results of this study showed that ceftriaxone was not very hygroscopic, but adding water to formulation affects significantly its immediate and long term stability. When dried after wetting to simulate a granulation process, ceftriaxone content remained stable. However, surprisingly grinding and compaction/crushing induced ceftriaxone drug content decrease after 6 month of accelerated aging (40°C/75%RH), but not before. X-ray diffraction showed that ceftriaxone crystalline lattice could be affected by high (but not moderate) compression forces. This study was further completed by a preliminary compatibility study of binary mixtures of ceftriaxone and various excipients to further establish a its of potential drug forms for further pharmaceutical development.

Biography

Tina Kauss (PharmD at University of Bordeaux and Master 2 of Pharmaceutical technology and Biopharmacy at University Paris 11) completed her PhD in 2007 at Bordeaux's University, followed by 3 years of postdoctoral studies in pharmaceutical development (pharmaceutical technology, biopharmacy and analytical chemistry). Since 2011 she is assistant professor of Pharmaceutical technology and Biopharmacy at the University of Bordeaux. She has published 16 papers in reputed journals of pharmaceutical development.

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