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Dissolution method development: R&D and QC holding hands

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Dissolution is an analytical test commonly used by the pharmaceutical industry to guide both formulation design and drug product quality control. When considering the development of a dissolution method, two main goals must be considered: 1) ensure consistent lot-to-lot quality for commercial products; 2) be suitable as QC tool for daily routine. The traditional dissolution approach often emphasizes its application in quality control testing and usually strives to obtain 100% drug release. In the presence of two oral granules formulations, with *in-vivo* data available, that showed differences in bioavalability, the initial method development was focused on a traditional dissolution approach. However, results showed that the method used had no disciminatory effect, therefore not reflecting the *in-vivo* data. A biorelevant dissolution method development followed - a pH shift method, where for the initial 30 minutes a low pH was applied followed by 90 minutes of neutral pH, was undertaken. The goal was to mimic the pH differences throughout the gastric system. The pH adjustment had been previously tested to ensure that the addition of NaOH 1M and PBS would shift the pH 1 to pH 7. The development of a robust method, that allowed the correlation with *in-vivo* data was successfully achieved and discrimination between prototypes was accomplished. The current work also shows that with proper development, pH shift dissolution methods can suit early development and routine QC lab needs.

Biography

Ana Mafalda Paiva has completed her PharmD from Pharmacy Faculty, University of Porto. She also has a Master's degree in Quality Control, from the same institution. Her work led to four papers in peer reviewed journals and several poster presentation at national and international scientific meetings, in the areas of nanotechnology, medicinal and analytical chemistry. She is working as an Analytical Chemist now, focusing analytical method development, at Hovione, Portugal.

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