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Abstract

In the pharmaceutical industry is very important to define the release profile of a generical compound. This kind of study can be done using some animals, as rat, but this type of method is tipically very expensive and morally not accepted, so is usefull to develop some new system to simulate the fisiology and the mechanics of human body.
The novel dissolution system used nowadays are standardized according to some national agencies called Pharmacopeia, Every country got an its Pharmacopeia, one of the most authoritative is the United State Pharmacopeia (USP).

In this work has been compared the release of a new pharmaceutic formulation used to reduce stomach ache and other pains in the gastric tract (the active ingredient of the test drug is bismuth subsalicylate), produced by the multinational Procter & Gamble, in two different dissolution system: the first one is the USP II, a conventional device similar to a perfect mixed vessel; the second one is an artificial stomach able to simulate the mechanics and the pH profile that really characterized the stomach during the digestion time.

As expected the profile is different between the two dissolution system. The results dimostrate that in the USP II the release grows gradually in the time and the dissolution ended around 40 minuts, while in the artificial stomach there is a maximum value of concentration of the active ingredient at 40 minuts due to the not perfect mixing. After this time the mixing is able to omogenized the concentration until a terminal value.

At the end we can say that the complete dissolution time in the two device is the same but in the second one there is a burst effect that generate the maximum value. This phenomenon characterezes tipically the couting drug and it can’t be neglected when we consider the dissolution profile of a pharmaceutic formulation.