GALENIC DEVELOPMENT OF GENERIC SPECIALITY WITH CONVENTIONAL RELEASE BASED ON ACARBOSE

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Background and importance

In the case of the development of a generic drug, the approach is based almost exclusively on galenic and analytical developments. However, to facilitate formulation, it is still necessary to go through a pre-formulation stage. Therefore, a generic drug must meet the same quality, safety and efficacy requirements as the originator drug.

Aim and objectives

The objective of our work consists on a pre-formulation stage followed by a formulation stage in order to arrive at an optimal, stable and effective galenic formula and to develop a generic oral anti-diabetic drug based on acarbose 50 mg.

Material and Methods

During the development of this generic specialty, a preliminary study of the raw materials was conducted (physico-chemical characteristics, rheological properties and compatibility study) in order to determine the quantitative formula and the manufacturing process. Then, 6 formulas were prepared in order to improve the flow time. The tablets obtained were tested for uniformity of mass, hardness, friability, disintegration time and dissolution in vitro. Subsequently, a comparative study of the dissolution profiles obtained with that of the reference drug was made by calculating the difference factor f2 and similarity f1 in order to determine the best formula.

Results

The method for the determination of the active substance by HPLC has been validated. The raw material has been well studied and the choice of excipients and the method of manufacture have been justified. Formula F5 having a friability percentage equal to 0,16 % (table 1), a disintegration time (5,9 min) (table 2) and a dissolution profile (Figure 1) similar to that of the reference specialty (f1 <15% and f2> 50%) was selected. It was considered the closest to the princeps (Table 3).

Table 1 : Results of the friability test

Essay	F1	F2	F3	F4	F5	F6
Friability (%)	0,03	0,7	0,1	0,1	0,16	1,2

Table 2 : Results of the disintegration time

Essay	F1	F2	F3	F4	F5	F6
Disintegration time (min)	5,7	6	6,5	6,1	5,9	5,1

Table 3 : Calculations of similarity and difference factors

	F1	F2	F3	F4	F5	F6
f2	36,61	40,47	35,52	36,60	55,81	37,73
f1	19,58	17,24	34,27	20,85	8,54	18,57

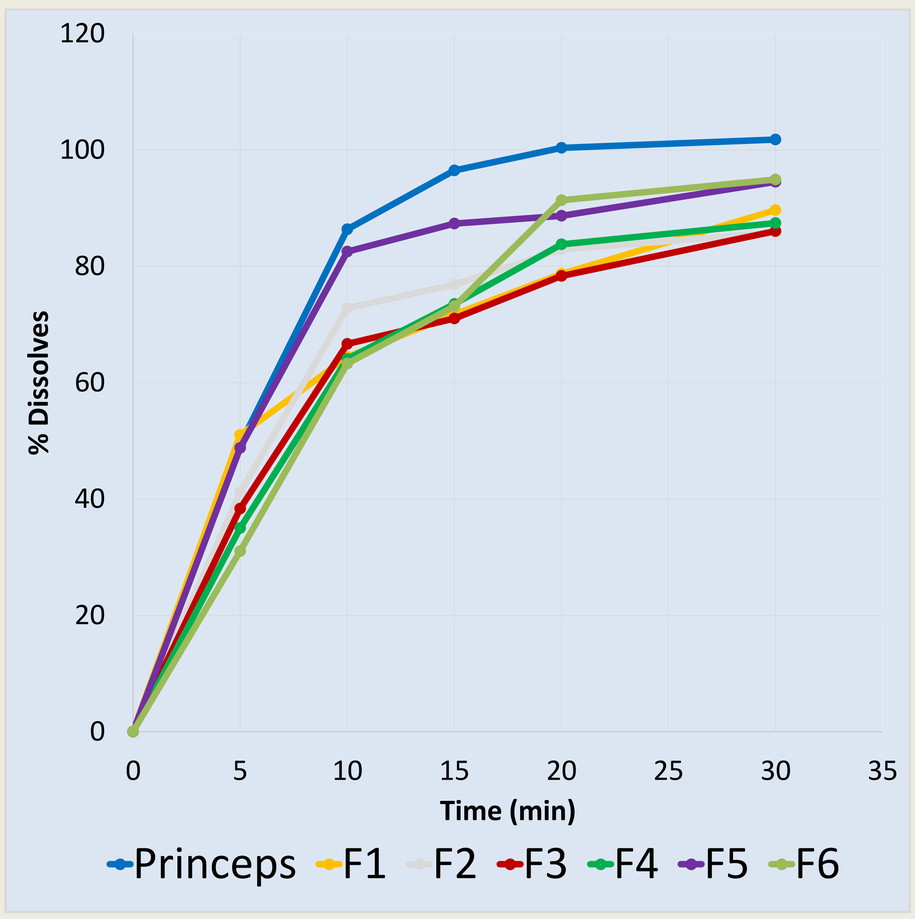

Figure 1 : Dissolution profiles of acarbose from formulas F1, F2, F3, F4, F5 and F6 compared to that of Princeps

Conclusion and relevance

The generic specialty formulated presented an equivalence in terms of in vitro dissolution with the reference specialty. Thus, comparative studies in 3 different pH environments need to be completed to judge this in vitro equivalence.

References and/or Acknowledgements
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