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Abstract Form

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USE OF MIXTURE DESIGNS FOR OPTIMIZING MDT AND DE OF FAST DISINTEGRATING PELLETS WITH POSSIBLE PEDIATRIC USE

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Purpose

Pellets are multi-particulate drug delivery systems consisting of small, almost spherical units, exhibiting unique technological and therapeutic characteristics, making them an appropriate choice for developing pediatric formulations. The objective of this study was the use of mixture experimental designs to achieve the desired dissolution pattern by combining three formulations of pellets with different release profiles. Mathematical models were then developed describing the relationship between the mixture ratios and their dissolution performance. Furthermore, this study evaluated two types of designs to compare their prediction accuracy.

Methods

The three different formulations of pellets, produced in a previous work, were mixed in various proportions according to two types of the mixture experimental design i.e. a Simplex-Lattice (14 experiments) and a User-Defined (23 experiments), in order to create mathematical models. The selected responses were the Mean Dissolution Time (MDT) and the Dissolution Efficiency (DE). Additional experiments to verify the predictions derived from the mathematical models in specific points of the Design Space were also carried out.

Results

It was found that it is possible to achieve any desired MDT and DE within the design space by simply controlling the ratio of the three pellet formulations with different release rates. The responses predicted from the mathematical models were found almost identical with the actual values derived from the verification runs. Both types of Mixture Designs provided statistically equivalent information regarding the prediction of MDT and DE within the Design Space.

Conclusions

The use of statistical experimental approaches like mixture designs were found very useful and economical tools for the adequate mathematical correlation of the formulation synthesis with the selected responses and provided the means for carrying out a pharmaceutical development exercise within the Quality by Design regulatory framework.