TECHNOLOGICAL CHARACTERIZATION OF FAST DISSOLVING FILMS MADE OF MALTODEXTRIN

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Purpose. Oral dispersible films are solid dosage forms which dissolve and/or disintegrate within less than 1 minute in the oral cavity avoiding the need of drinking or chewing.
Films with suitable mechanical properties are obtained by addition of a plasticizer, namely glycerine, to maltodextrins.
However, the main critical aspect is that these films tend to become less flexible over time and the stiffening of the film may affect stability and handling of the product.
The objective of this work is to stabilize the mechanical properties of the films over time.

Methods. A study performed by ATR-FTIR spectroscopy aimed to evaluate the possible interactions between maltodextrins and BTY28, a novel water insoluble excipient.
Five placebo formulations were prepared, containing increasing percentages of BTY28 (1-20% w/w) and the performances of the formulations obtained were compared with those of a film free from this additive. In particular, the films were studied in terms of time of disaggregation and tensile properties.
The most suitable formulation was chosen to prepare orodispersible films containing, as model drug, Diclofenac Epolamine. In this case, the films obtained were characterized by determining drug content, impurities and dissolution profile, in addition to the properties reported for placebo films.
The stability of the films was followed over a six months period on samples stored, both in normal and accelerated conditions, in accordance with the ICH guidelines.

Results. A comparison between the ATR-FTIR spectra of binary mixtures of maltodextrins and BTY28 highlighted that BTY28 was able to modify the three-dimensional organization of maltodextrins by forming hydrogen bonds.
As expected the MDX films stiffened in the first three months of storage; the addition of BTY28 in the 3-5% range permitted to obtain dosage form with good mechanical properties, which resulted stable over time.
Moreover, the addition of this additive didn't affect dissolution and disaggregation of the films loaded with Diclofenac Epolamine, and its chemical stability.

Conclusions. The use of BTY28 permitted to improve the stability of mechanical properties of film made of maltodextrins and therefore this formulation could be advantageously used for the production of fast dissolving film.