

## Streszczenie w j. angielskim

The aim of this study was to develop the composition and technology of manufacture for oral films with levocetirizine dihydrochloride and with loratadine by the semi-solid extrusion method. Antihistamine APIs were used and examined in two doses: 1mg and 2mg levocetirizine dihydrochloride and 2 mg and 4 mg loratadine.

HPLC (high-performance liquid chromatography) with isocratic elution was used to quantify the active substances. The method was validated in terms of specificity, accuracy, precision, and linearity. Levocetirizine dihydrochloride was introduced into the formulation in dissolved form, whereas loratadine particles were incorporated in crystal form. The diameter of the oral films has been designed so that they would fit on the inside of a child's cheek.

An important aspect of the study was to give the oral films certain mucoadhesive properties allowing their adhesion to the cheek. Sodium alginate has been introduced into the formulation to achieve that. Research carried out on texture analyzer, and mucoadhesion test system have shown that the oral films have mucoadhesion properties.

The examination carried out with the use of an electronic tongue has confirmed that neotame and  $\beta$ -cyclodextrin can successfully mask the bitter taste of API.

In vitro release studies have shown that oral films meet the Pharmacopoeial requirements relating to the release of API in an unmodified oral solid dosage form. Raman spectroscopy, DSC, and XRD test results point to a formation of inclusion complex between  $\beta$ -cyclodextrin and levocetirizine dihydrochloride. Microscopic analysis as well as XRD and Raman spectroscopy, have confirmed an even dispersion of loratadine particles in the oral films. DVS testing has indicated a necessity to use barrier packaging for both types of oral films.

Oral films with APIs had a lesser mechanical strength than the ones containing placebo. Moreover, oral films containing levocetirizine dihydrochloride were more durable than the ones containing loratadine.

Keywords: oral films, pediatric dosage forms, levocetirizine dihydrochloride, loratadine, 3D printing

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