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Effect of maize starch excipient properties on drug release rate

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Abstract

The aim of the work was to determine the influence of pregelatinized maize starch properties on the dissolution rate of caffeine. The intrinsic dissolution rate apparatus was used to investigate the process of drug dissolution. Dissolution profiles of caffeine mixed with 5 different maize starch samples, using caffeine : starch ratio (4:1), were measured. The dissolution profiles of all caffeine-starch mixtures are presented, as well as the results of the mathematical model, consisting of the equations for caffeine concentration change and for the starch layer change in time. The values of 3 parameters of the dissolution model were estimated using non-linear regression analysis. Caffeine effective diffusivity in swollen starch layer was found to be strongly related to the starch swelling capacity.

Keywords: Intrinsic dissolution; mathematical modeling; binder; release rate; diffusion; caffeine; maize starch

1. Introduction

Starch represents one of the most widely used pharmaceutical excipients. However, it can be also considered one of the most complicated excipients as its physicochemical and functional characteristics can vary a great deal even among starch samples of similar origin. Although the QC requirements on

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pregelatinized starch properties are relatively tight, still the limits are wide enough to have substantial effect on API release from the dosage form. Pregelatinized maize starch is commonly used as a binder-disintegrant in immediate release tablet formulations, but it was also considered for sustained release formulations [1-3]. Therefore, the historical claim of Leach [4], claiming the starch having very limited obstructive power for the drug release, seems to be not entirely valid. Also Levina [5] reported that pregelatinized maize starch contributed to retardation of both soluble and slightly soluble drugs compared to microcrystalline cellulose or spray-dried lactose. Onofre [6] further examined the effects of starches having different cross-linking on sustained release from matrix type tablets and observed substantial differences among the starch samples. However, modified starches from different sources showed different sustained release properties that were not a simple function of cross-linking or any other single starch parameter. Hence, the aim of this study was to examine the effect of different starch samples on the release rate of the active ingredient, describe the release by the mathematical model, and examine the correlation among the key model parameters and selected functional characteristics of the maize starch.

Nomenclature

A	Wood's apparatus die cross-section surface area, cm^2
c	mass concentration in dissolution medium, $g.cm^{-3}$
D	diffusion coefficient, $cm^2.s^{-1}$
D_{ef}	effective diffusion coefficient in the swollen starch matrix, $cm^2.s^{-1}$
L	Wood's apparatus die diameter, cm
$R_{ST,dis}$	linear rate of starch layer dissolution/decay, $cm.s^{-1}$
t	dissolution time, s
U	superficial liquid velocity, $cm.s^{-1}$
V	volume, cm^3
w	mass fraction of caffeine in caffeine-starch mixture, -
δ	thickness of the swollen leached starch matrix, cm
δ_{HL}	hydrodynamic layer thickness, cm

Indices

0	initial value
CAF	caffeine
ST	starch
*	equilibrium – saturated solution