

# Coated pellets with controlled glucose release in treatment of children with diabetes



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## Background

A diet plan usually includes meals with suitable glycaemic index together with sophisticated insulin delivery for balanced saccharides-insulin intake. Nevertheless, the need of controlled sugar release is urged in specific day-to-day life situations, especially for young children with diabetes. Nocturnal hypoglycemia, parental fear of insufficient snack intake in the nursery or sports with prolonged race periods are typical examples of these life situations.

## Objectives

1. To achieve a dosage form with controlled release of glucose with 4, 6 and 8 hours lag time offering a chance to substitute snacks or other meals in advance.
2. To decrease inconveniences in lifestyle and improve the therapy and compliance of children with diabetes and their parents.

## Methods

A dosage form with controlled glucose release was successfully prepared. Targets of the research were lag time of 4, 6 and 8 hours (Fig. 3), as well as short release period of 2-4 hours. The variables of the dosage form were an optimal diameter of the pellet (Fig. 1), resistance of the coat (Fig. 2), volume, taste and form acceptable for swallowing. These variables were refined via pharmaceutical methods for optimal efficiency in patient use.

Figure 1: A diameter of pellets; electron-microscopy

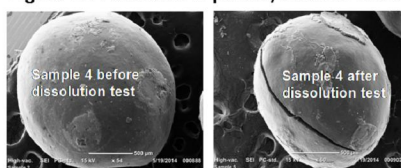
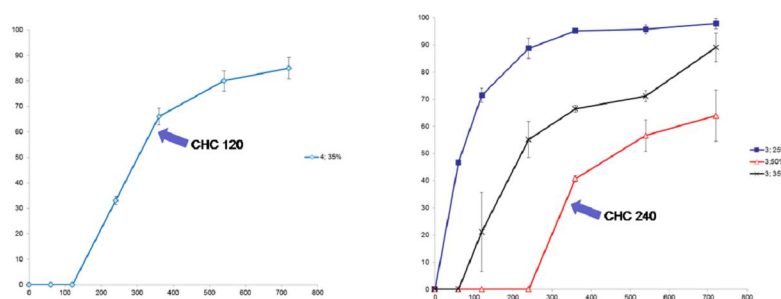


Figure 2: Composition of pellets

Sample/Composition (g)	3	4
Glucosum anh.	75.0	80.0
Avicel PH 101		15.0
PEG 6000	25.0	
Vivastar 5 000		5.0
Surelease (solid)	33.3	53.9

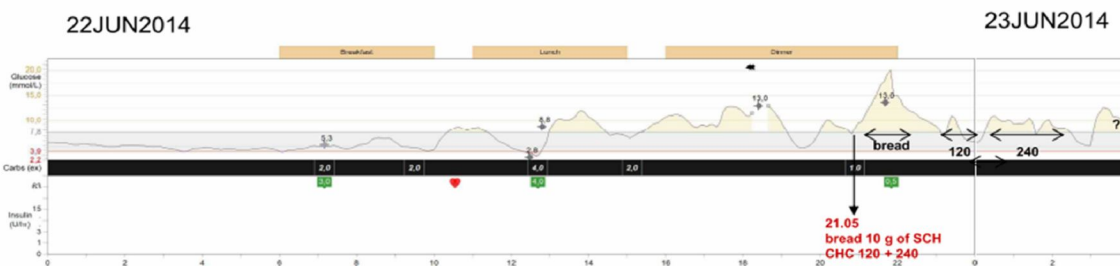
Figure 3. Preliminary tests with pellets of 2 and 4 hours lag times (arrows)



## Results

- One, two or more exchange units (10 g of saccharides) in the form of pellets can be easily added to standard meals, e.g. yoghurt.
- Pellets (clinically powder) don't cause abdominal discomfort.
- In CGM studies, the formulation prevents nocturnal hypoglycemia, as documented on Fig. 4.

Figure 4: CGM with documented rise of glycaemia, when adding pellets of the 120 and 240 minutes lag time



## Discussion

- A successful dosage form was achieved with controlled release of glucose.
- Sugars with specific easy-to-explain lag times can be prepared, as education is essential for an appropriate use of the dosage form.

## Conclusions

The aim of the study was to prepare and test pellets with controlled glucose release to substitute meals in advance.

1. Pellets with controlled release of glucose can be prepared and serve as an acceptable alternative means for diabetes treatment.

### Acknowledgement:

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