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Development of Micropellets for Buccal Drug Delivery

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Introduction: Pellets are an attractive dosage form in the gender specific and pediatric therapy, since they offer the possibility of patient adapted dosing. Additionally, they are easily swallowed and unpleasant taste masking by coating is facilitated due to their smooth and homogenous surface. The development of disintegrating pellets is a new and innovative technology. The main advantage of this type of dosage form is the circumvention of the hepatic and the first pass metabolism [1]. In the present study Ludiflash®/Kollidon® CL-SF (crospovidone) mixtures were used to prepare disintegrating micropellets via a wet extrusion/spheronization process.

Methods: Powders were blended and wetted with different water/ethanol mixtures (i. e., 10% 20%, 30%, 40% and 50% ethanol). The wet mass was subsequently extruded through a 0.8 mm multihole die plate and spheronized at different speeds for 2-4 minutes. Finally pellets were dried using three different methods (i.e, desiccation, tray drying and fluidized bed technology). The disintegration behavior in water at 37 ± 0.5 °C was evaluated according to Pharm. Eu. 6.0 2.9.1. In addition, the mechanical characteristics (tensile strength, friability) and the pellet shape were investigated.

Results: For pellet formulations containing 5% Kollidon® CL-SF a minimum ethanol fraction of 30% in the granulation fluid was required for successful extrusion/spheronization. At lower alcohol contents extensive liquid movement occurred during extrusion resulting in non-reproducible process conditions. Pellets prepared with 30% and 40% ethanol disintegrated within 1 minute. Using 50% ethanol, however, yielded in increased disintegration times (>1min). Pellets containing 10% crospovidone were successfully prepared with all granulation liquids under investigation. Disintegration times exceeded 1 minute when the ethanol fraction was higher than 20%. All pellet formulations exhibited sufficient mechanical stability and an aspect ratio below 1.2.

Conclusion: Ludiflash® in combination with either 5% or 10% Kollidon® CL-SF is a promising extrusion and spheronization aid for the preparation of pellets showing disintegration times below 1 minute.

- [1] Birudaraj R, Berner B, Shen S, Li X. Mechanistic Studies on transport pathways. J Pharm Sci. 2005; 94: 70–78. doi:10.1002/jps.20208