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DEVELOPMENT OF EQUIPMENTS FOR LARGE-SCALE PRODUCTION OF FAST DISSOLVING ORAL FILMS

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Introduction: The fast dissolving oral films, also know as oral strips (OS), were developed on the early 70's, as an alternative to more conventional pharmaceutical forms. One of it most important characteristics is a disintegration time of less than one minute. When the OS gets in contact with the saliva they disintegrate almost immediately, becoming a solution easily swallowed, especially by elderly patients and children. [1] The OS development involves the choice of an effective polymer, the addition of a suitable plasticizer, and other minor ingredients, like surfactants and flavor agents, being the manufactory technology based on already existing methods that are currently used on others industrial techniques, for example on transdermal production. The most important manufacturing methods are by extrusion or solvent casting. [2,3]
Objective: The development of equipments for large-scale OS manufacturing, aiming quality, efficiency and speed, thereby improving a technology to meet a likely future demand in the pharmaceutical industry.
Materials and Methods: In partnership with mechanical engineering students was projected an extrusion machine and an equipment for OS production by lamination and solvent casting. After the specification of boundary conditions, the necessary calculations for the equipment assemblage were done, and then from calculations the drawings were made using CAD (SolidWorks software, 2009 version). The ideal combinations between polymers and plasticizer were selected based on previous tests, and through calculations and experimental design studies we selected the best conditions for production.
Results and Discussion: Initially we began with a theoretical analysis of the interaction between the equipment project and their performance. The machine size was selected considering a directed proportion between the blade size and the desired production. The die was projected in accordance to the OS size and its internal shape was determined by the ease of machining. The feed screw had cylindrical shape, decreasing channel depth and constant pitch, where the nominal diameter was kept constant. The pitch was decreased, what considering constant PMR represented a decrease in productivity, but also led to a better polymer homogeneity. For the production of OS by the casting solvent method, after the calculation of mass transfer by external flow convection, was produced an acrylic structure, the rolling mills and a drying system. It was found that by the extrusion method it is possible to achieve greater productivity, but in contrast by the casting solvent the OS gathered a better quality, as it was possible to developed thinner OS with a shorter disintegration time. Concerning the solvent casting method, it was also noted that drying is a critical step for the manufacturing of the OS, since if it's improperly made it can affect both visual aspect as tensile strength and disintegration time.
Conclusions: The development of the manufacturing process of OS is a technology that is still relatively untapped by the pharmaceutical industry and requires a combination of theory and practical experience, where the products and their formulations are simultaneously developed with the processes that gives rise to them. Moreover, the application of statistical techniques is essential for significant improvements on process performance.

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