SUPERCRITICAL-FLUID MELT-EXTRUSION OF BIODEGRADABLE AND BIOCOMPATIBLE POLYMERS

Vigh T.[1*], Bocz K.[1], Sauceau M.[2], Nagy Z. K.[1], Fages J.[2], Marosi G.[1]

[1] Department of Organic Chemistry and Technology, Budapest University of Technology and Economics, Budapest (Hungary)
[2] RAPSODEE Research Centre, École des Mines d'Albi-Carmaux, Albi (France)
** tvigh@mail.bme.hu*

Melt extrusion is a widely-used process for converting a raw polymer into a product of uniform shape and density by melting and forcing it through a die under controlled temperature and pressure. In the *plastic industry* the main application of melt extrusion is compounding and/or shaping of polymers (e.g. production of films). Similarly, melt extrusion can be employed in the *pharmaceutical industry* to produce medical devices and to disperse drugs in an amorphous biocompatible polymer matrix of orally administered solid dosage forms without any organic solvent. This way solid solutions or solid suspensions can be formed, even with high drug load.

Recently, the scope of melt extrusion has been widened by the use of supercritical carbon dioxide (sc. CO_2), which acts as a plasticiser in the barrel by decreasing melt viscosity. Thereby it can increase productivity at lower temperatures and prevent the degradation of the processed materials. Another advantage of sc. CO_2 is that by making use of its expansion, controlled foaming of the polymer melt can be realised without leaving any residue.

In this study, foaming of biodegradable and/or biocompatible polymers (polylactic acid and Eudragit E) was carried out and examined regarding the relationship between the foam structure and the process parameters (polymer flow-rate, sc. CO_2 fraction, extrusion temperature and pressure) as well as the filler quality. Furthermore, selected samples were analysed for their structural properties (e.g. apparent density, morphology, pore size distribution), mechanical properties and crystallinity (by X-ray diffraction, Raman mapping and thermal analysis). The foaming behaviour of the Eudragit E and PLA foams was found to be largely affected by the presence of additives (e.g. the active ingredients spironolactone or prednisolone, or fillers, such as cellulose) and by the processing temperature. The porosity–temperature relationship was established for all the processed systems. By this optimisation even >95% porosity could be achieved for PLA-based systems and 92% for Eudragit E-based systems.

Temperature could be notably decreased by making use of the reversible plasticising effect of sc. CO_2, and this procured an increase in drug purity in the case of the pharmaceutical dosage forms. The increased specific surface area of the Eudragit E formulations (together with drug amorphisation) resulted in an enhanced dissolution. High porosities are also advantageous in the plastic industry, e.g. when insulation materials are produced.

ISBN 978-963-313-179-4