SUPERCRITICAL ANTISOLVENT MICRONIZATION OF LEVOTHYROXINE SODIUM

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Levothyroxine sodium is a synthetic hormone produced to replace thyroxine (T4) for people who have thyroid gland hypofunction. Its commercial formulations provide variable dissolution rates depending on particle size and morphology, affecting absorption by the human body. So, it is important to modulate morphology, particle size and size distribution, in order to achieve better drug performance. Supercritical fluids micronization processes have been extensively investigated as an alternative to product micro and nanoparticles of pharmaceuticals with narrower size distributions and no residual solvent in the final product. Supercritical antisolvent (SAS) is one of the most promising among these processes. In this work, micronization of levothyroxine sodium by SAS is investigated using supercritical carbon dioxide as antisolvent and ethanol as solvent. Experimental runs were carried out in a bench scale SAS unit recently at the Federal University of Bahia. Operating conditions above and below the mixture critical point were tested. Preliminary scanning electron microscope (SEM) analysis of the micronized powder of levothyroxine sodium shows spherical micro and nanoparticles depending on the temperature, pressure and initial drug concentration in the organic solution.

Keywords: Supercritical carbon dioxide, micronization, levothyroxine sodium, ethanol.

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