

Drying Methods for the Removal of Residual Solvents from Solvent Induced Amorphous Paclitaxel

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This study investigated the effect of solvents on the formation of amorphous paclitaxel and proposed the efficient strategy for removing the residual solvents from solvent induced amorphous paclitaxel. Amorphous paclitaxel was produced by evaporation with solvents (methylene chloride, toluene, pentane, methyl t-butyl ether, chloroform, acetonitrile/hexane (1:2, v/v)). The residual pentane and hexane levels easily met the ICH-specified values (5000 ppm and 290 ppm) by simple rotary evaporation. In addition, when the vacuum-dried sample was subjected to microwave-assisted drying, the ICH requirements for methylene chloride (600 ppm) and acetonitrile (410 ppm) could be met by drying for 23 h at 200 W and 3 h at 200 W. However, the residual toluene, methyl t-butyl ether and chloroform did not meet the ICH-specified values (890 ppm, 5000ppm, 60ppm). The shape and size of particles varied according to the solvent used in the solvent evaporation process. Acknowledgment This research was supported by Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science and Technology (Grant Number: 2015016271).