

The use of valeryl chloride and methanol for the deprotection of 1b yielded highly pure compound 2b, and subsequently compound 4b did not need to be isolated. This process does not involve chromatographic purification and reverse osmosis. The use of Pd/C (1.5 w/w based on 3b) in the hydrogenolysis of compound 4b in the Nishino method resulted in a palladium residual level of 430 ppm in 5 as well as 4 ppm in the sterile Active Pharmaceutical Ingredient (API) 5. The magnesium chloride previously used in the catalytic hydrogenolysis of 4b evidently crystallized along with 5, and presence of the salts required separation using column chromatography, a process which is typically not favored on a commercial scale.