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Pharmaceutical scale and green process for the synthesis of anticancer drug Pomalidomide

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Pomalidomide (PML), chemically (RS)-4-amino-2-(2,6-dioxo-3-piperidiny)-1H-isoindole-1,3(2H)-dione, is a small molecule analog of thalidomide developed by Celgene Corporation for the treatment of hematological and connective tissue diseases by oral administration. It is a potent second-generation oral immunomodulatory agent with antineoplastic activity, showing significant activity in multiple myeloma patients with disease refractory to lenalidomide and bortezomib. We develop a new route for the preparation of pomalidomide on the pharmaceutical scale and polymorphic form based on Celgene Corporation. The synthetic procedure starts from 4-nitroisobenzofuran-1,3-dione and 3-aminopiperidine-2,6-dione hydrochloride via a 2 step reaction resulting in a total yield of 95% with a high HPLC purity of 99.98%.

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