Design and invitro evaluation of 10 mg tablets of Rosuvastatin calcium

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Abstract: Rosuvastatin is a member of the last generation of statins which because of its advantages is used in many fields like reducing the atherosclerosis progression rate and prevention of heart and vascular diseases. Because of its higher potency for reducing LDL-C and increasing HDL-C as well as more inhibitory effects on producing hepatic cholesterol, Rosuvastatin has some advantages compared to other statins. For this reason, and also because of lack of local production of Rosuvastatin tablets in Iran, we decided to study different formulations of this drug in order to find the best formulation, with similar properties, to the branded product, Crestor®. First, pre-formulation studies were performed. Because of the advantages of direct compression method, this method was used for producing the formulations. In order to produce a similar formulation to the brand product, first the effects of different amounts of Crospovidone as the disintegrating agent were studied. Then the effects of different amounts of Tri-Basic Calcium Phosphate as a stabilizer were studied. In the end, the effects of changing the type of stabilizer were studied. Physicochemical tests have been done on all of the formulations. Also stability test under stress condition was performed on some of the formulations. The results of dissolution and assay test were studied by HPLC method. At the end, validation of the HPLC method used in this study was performed. Results show that the amount of 5% of Crospovidon as the disintegrating agent and 25% of Tri-Basic Calcium Phosphate as a stabilizer make the dissolution profile of the formulation most similar to the brand. By reducing the amount of stabilizer, more proportion of active ingredient was destroyed. All results of validation tests were in acceptable range. According to the results, among the three groups of formulations, A, B and C, the C₁ formulation with a similarity factor of more than 94% was identified as the best formulation.

Keyword: Rosuvastatin, Direct Compression, HPLC, Validation