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DEVELOPMENT OF A DISSOLUTION METHOD FOR ATORVASTATIN TABLETS BASED ON IN VIVO DATA

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Introduction: The hiperlipedemia is the major cause of atherosclerosis and diseases associated with atherosclerosis such as coronary heart disease (CHD), stroke and peripheral vascular disease. The incidence and absolute number of annual events are likely to increase over the next decade due to epidemic obesity and an aging of population.[1] Statins are the most prescribed class of lipid lowering in the world for reducing cardiovascular risk and progression anatomic atherosclerosis. These benefits have been attributed mainly to its remarkable decrease in cholesterol of low density lipoprotein (LDL).[2]

Objective: Develop methods for dissolution of coated tablets of atorvastatin (figure 1), whose conditions have analogy with in vivo data from the bioavailability of the drug of two different formulations and the reference product, using high performance liquid chromatography (HPLC), ultraviolet spectrophotometry (UV) and capillary electrophoresis (CE) for the quantification of atorvastatin in different dissolution media in assessment.

Materials and Methods: Studies will be undertaken with the aim of developing a dissolution method for coated tablets of atorvastatin, by assessing the following parameters: device most suitable for the formulation, different dissolution media (use of biorrelevantes media), volume of medium, speed agitation, and sampling time for dissolution profiles in order to obtain a discriminative method, accurate and robust. The methodologies will be validated according to ICH and USP. The quantitative analysis of atorvastatin will be conducted by HPLC, UV and EC. The results of the dissolution will be compared with the *in vivo* data of two different formulations and reference product in order to obtain parameters corresponding to the pharmacokinetic parameters, using appropriate correlation. To date samples from pilot batches are in development and in house standard is being featured. The establishment of this type of correlation data may allow the replacement of *in vivo* studies, required for bioequivalence studies, in the context of formulation development, changes in manufacturing process and post registration. For these reasons it is expected that the contributions arising from the realization of this project will be significant, ensuring the safety and efficacy of pharmaceutical products.

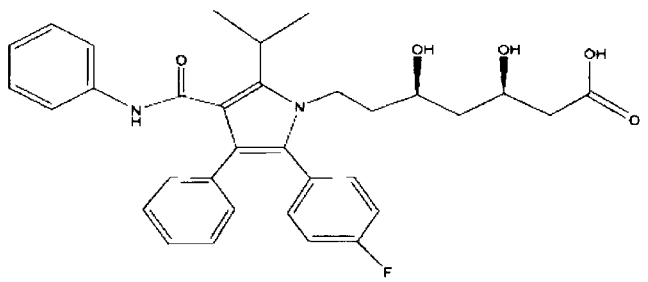

Figure 1. Chemical structure of atorvastatin

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