



**INTERNATIONAL E-CONFERENCE CONTEMPORARY
PHARMACY: ISSUES, CHALLENGES AND EXPECTATIONS**

23rd OF OCTOBER 2020, KAUNAS

ABSTRACT BOOK

2020 autumn

October 23rd, 2020

Kaunas, Lithuania

The international conference “CONTEMPORARY PHARMACY: ISSUES, CHALLENGES AND EXPECTATION. 2020 AUTUMN” is organized by Lithuanian University of Health Sciences, Faculty of Pharmacy, Department of Drug Technology and Social Pharmacy.

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ISBN 978-9955-15-669-7

2020, Kaunas

Language of abstracts was not corrected.

Study on the development of a solidified lipid-based formulation for atorvastatin calcium

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Introduction: Atorvastatin calcium (ATC) is one the most frequently prescribed therapeutic agents. Despite its high GIT permeability ATC has only 14% bioavailability after oral administration which is attributed to its poor aqueous solubility. To solve this problem the drug can be dissolved in the appropriate lipid-based liquid system which then is incorporated in a dosage form convenient for patients. Thus, our study is aimed to select the excipients for dissolving ATC and further solidifying the resulting lipid-based solution in order to obtain tablets with improved bioavailability.

Materials and methods: Micronized amorphous ATC (Cadila Healthcare Ltd., India) was used. Optical microscopy was utilized as a preliminary screening tool in ATC solubility evaluation. The exact solubility of ATC was established by determination of a solvent amount required for visually registered complete dissolution after heating at 60°C and cooling at a room temperature. The adsorption capacity of three highly porous carriers was determined as their minimum quantity enough to convert a lipid-based solution into a free-flowing powder that doesn't stick to a mortar and pestle.

Results. Microscopic screening allowed to select oleic acid (OIA) as an oil component, polysorbate-80 (PS80) as a surfactant and macrogol 400 (M400) as a cosolvent. Various ratios of these excipients also were microscopically evaluated and a system consisting of 75% OIA and 25% PS80 and M400 mixture (1:1) showed the best solubilizing performance with exact ATC solubility of 40.0 mg/g. The solidification of 1 g of ATC lipid-based solution required 0.210, 0.308 or 0.533 g of Syloid 244 FP, Neusilin US2 or Neusilin UFL2, respectively.

Conclusions: Excipients for dissolving lipophilic drug atorvastatin calcium have been selected. The next stage of the research will be devoted to the tablet formulation studies using different types of solid carriers for choosing the composition with the best mechanical and release properties.

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