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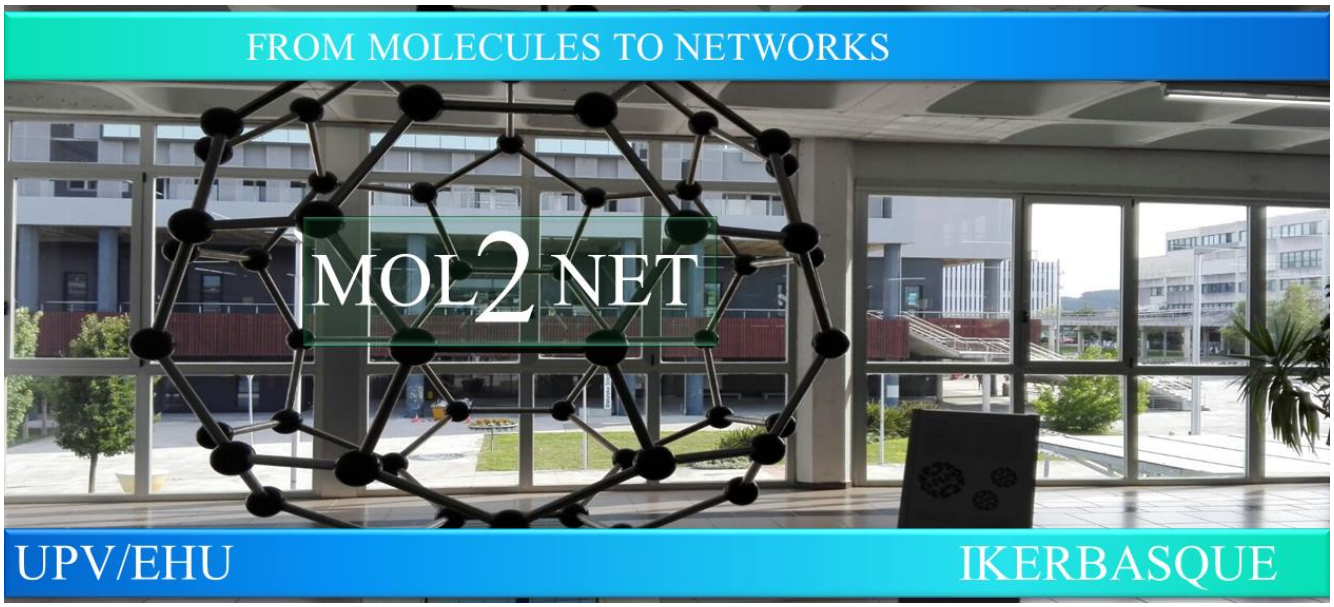

DEVELOPMENT OF THE SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF ROSUVASTATIN IN TABLETS BY USING BROMOPHENOL BLUE

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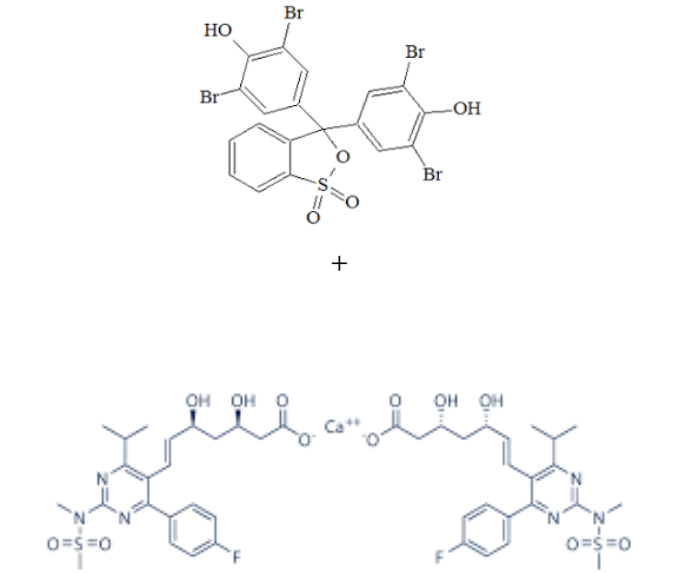
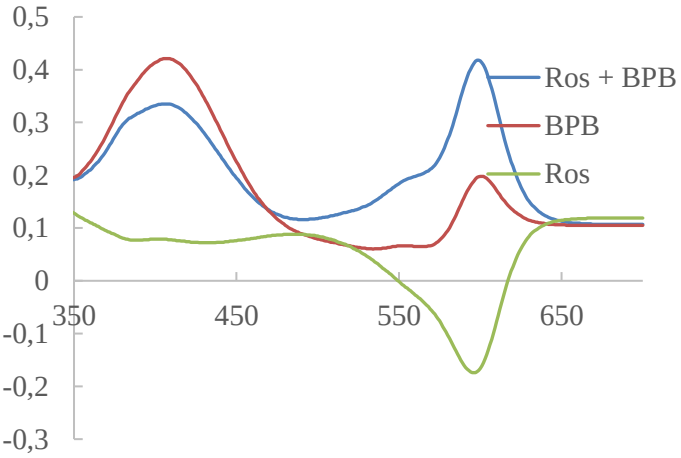
Graphical Abstract	**Abstract.** *Rosuvastatin, bis[(3R,5S,6E)-7-[4-(4-fluorophenyl)-2-(N-methylmethanesulfonamido)-6-(propan-2-yl)pyrimidin-5yl]-3,5-dihydroxyhept-6-enoate], - sparingly soluble in water (17.96 mg/mL), Log P = 0.13. Differently from other statins, the addition of a stable polar methane sulfonamide group in the structure of rosuvastatin confers relatively low lipophilicity. The European Pharmacopoeia (EP) has a monograph*





on rosuvastatin calcium and rosavastatin tablets. EP regulates the quantitative determination of rosuvastatin in tablets by HPLC. Nowadays, chromatographic techniques are undoubtedly the most modern in terms of specificity, correctness and precision. However, there are laboratories that do not have expensive equipment and for them spectrophotometric methods of analysis are more accessible. Spectrophotometric methods are often used as alternatives in the implementation of quality control of medicines. The scientific literature describes a number of spectrophotometric methods for determining rosuvastatin in dosage forms by its own absorption. Considering the advantages of using sulfophthalein dyes in pharmaceutical analysis, the spectrophotometric method for determining rosuvastatin by reaction with bromocresol green, developed by Syrian scientists, deserves attention. However, the proposed technique involves the use of chloroform as a solvent, which does not confirm to the principles of «green» chemistry. The chemistry of sulfophthalein dyes and the development of spectrophotometric methods for the determination of APIs in dosage forms based on interaction with sulfophthalein dyes is interesting and not easy, as it requires the use of certain approaches to the research methodology. At the stage of preliminary research, we tested many sulfophthalein dyes and the results obtained when using bromophenol blue (BPB) were interesting, therefore, the aim of the work was to develop and validate a spectrophotometric method for the determination of rosuvastatin in tablets based on the reaction with BPB.

Material and methods. Analytical equipment: two-beam UV-visible spectrophotometer Shimadzu model -UV 1800 (Japan), software UV-Probe 2.62, laboratory electronic balance RAD WAG AS 200/C. The following APIs, dosage forms, reagents and solvents were used in the work: pharmacopoeial standard sample (CRS) of rosuvastatin calcium (Sigma-Aldrich, (≥ 98%, HPLC)), BPB

	(Sigma-Aldrich, (≥ 98%, HPLC)), "Rosuvastatin" tablets 10 mg, methanol (Honeywell, (≥ 99.9 %, GC)), ethanol (Honeywell, (≥ 99.9 %, GC)), chloroform (Honeywell, (≥ 99.9 %, GC)), acetonitrile (Honeywell, (≥ 99.9 %, GC)), and ethyl acetate (Honeywell, (≥ 99.7 %, GC)). *Results and discussion. A spectrophotometric method for the determination of rosuvastatin by reaction with BPB in a acetonitrile solution using the absorption maximum at a wavelength of 595 nm has been developed. Stoichiometric ratios of reactive components were established, which were 1:1. The developed method for the quantitative determination of rosuvastatin was validated in accordance with the requirements of the SPhU. The analytical method was linear in the concentration range of 7.99-23.97 µmol/L. According to the «greenness» pictogram of the analytical method using the AGREE method, the score was 0.79 and indicates that the proposed spectrophotometric method for the determination of rosuvastatin was developed in compliance with the principles of «green» chemistry.* *Conclusions. The proposed spectrophotometric method has a low negative impact on the environment and can be applied for the purposes of routine pharmaceutical analysis.*