VII. SUMMARY

The growing interest in the quality of medicines and the large number of decisions holding or withdrawing drugs from the Polish market in recent years, make the compliance of a series of pharmaceutical preparations with specifications a matter of public interest. Medicines registered in a given territory can properly serve patients only if they are free of quality defects and given in strictly defined doses, in accordance with the medical regulations. In this light, the patient's safety is guaranteed by routine control, which is possible only thanks to the existence of modern, accurate, precise and uncomplicated analytical methods that are also characterized by a short time of analysis.

The research presented in the paper aimed to propose methods of quantitative analysis of pharmaceutical substance based on derivative spectrophotometric techniques and high-performance thin-layer chromatography with densitometric detection, which are successfully used in modern pharmaceutical analysis.

The assumed goal of the work was accomplished through a comprehensive literature review indicating the rightness of the subject, and then developing and performing analyzes step by step using both spectrophotometric and chromatographic methods of the following pharmaceutical substances: lormetazepam, trimetazidine, amrinone and milrinone in pharmaceutical preparations and / or laboratory prepared model mixtures. Model mixtures of active pharmaceutical ingredients with excipients were prepared in accordance with the Summary of Product Characterisics, pharmaceutical preparations were pulverized, series of extractions were made and solutions for the calibration of both methods were prepared. Zero order spectra were recorded with a Hitachi U-2800 double beam spectrophotometer (Tokyo, Japan), subsequent derivatives of basic spectra were calculated using UV Solution 2.0 software (Hitachi High-Technologies Corporation, Tokyo, Japan), and the analytical wavelengths were selected. In the case of the chromatographic method, the chamber was saturated with a mobile phase, the chromatogram was developed using horizontal technique and after drying of the plate the absorbance was measured using a Desaga CD 60 densitometer. The densitogram was generated and peak area was calculated using the Pro-Quant software (SARSTEDT AG & Co., Nümbrecht, Deutschland). For both elaborated methods, the accuracy and precision values were calculated on the basis of calibration curves, and the content of active pharmaceutical ingredients in pharmaceutical preparations was also

calculated. Statistical analysis was performed using Statistica® 13.0 (StatSoft, Tulusa, Oklahoma, USA).

Thanks to the proposed methodology, the content of lormetazepam and trimetazidine in pharmaceutical preparations was calculated, which confirmed that they meet the pharmacopoeial requirements for the content of active substance, (according to Polish Pharmacopoeia XI, the content of active substance is to be in the 85-115% range) [20].

The results presented in this work indicated that derivative spectrophotometric and high-performance thin-layer chromatographic methods can be successfully used for the routine control of the content of active substance in its dosage form. In terms of accuracy and precision for given applications, they do not differ from high-performance liquid chromatography, that is more demanding in terms of finance, time and equipment.