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Development of Fourier Transform Infrared Spectrophotometric Method for Quantification of Simvastatin, Atorvastatin, and Rosuvastatin in Marketed Tablet Preparations

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ABSTRACT. Marketed pharmaceutical dosage forms must be checked to ensure that the drug in distribution meets the quality requirements. The Fourier transform infrared spectrophotometric method will provide new innovations which are low cost, environmental friendly, simple, and rapid for analysis. The aim of this research was to develop a single analytical method that can be used to determine levels of three different statin derivatives (simvastatin, atorvastatin, and rosuvastatin) in tablet preparations. The method used in this study was Fourier transform infrared spectrophotometric, a very simple sample preparation stage by solvent extraction with minimal solvent extraction without potassium bromide and without pellet press. The specific wave numbers of simvastatin, atorvastatin, and rosuvastatin were determined between 4000 cm^{-1} to 650 cm^{-1}. The Fourier transform infrared spectrophotometric method had been successfully developed and successfully applied to the determination of levels of simvastatin, atorvastatin, and rosuvastatin in marketed tablet preparations containing single active pharmaceutical ingredient. The specific wave numbers of simvastatin, atorvastatin, and rosuvastatin obtained was 1712.7 cm^{-1}; 1660.5 cm^{-1}; and 965.4 cm^{-1}, respectively. The results obtained in the content determination based on the peak height and peak area fulfill the requirements for active pharmaceutical ingredient assay ranging from 90.00% to 110.00%. The developed method has also been validated for accuracy, precision, specificity, linearity, range, limit of detection, and limit of quantitation. Thus, this method can be a valid alternative method, cheap, green, easy, and fast in determination of the levels of simvastatin, atorvastatin, and rosuvastatin in tablet preparations.

Keywords : atorvastatin, FTIR, rosuvastatin, simvastatin, tablet

INTRODUCTION

Drugs for the treatment of dyslipidemia that are widely available commercially in pharmaceutical tablet preparations are statin derivatives, likely simvastatin, atorvastatin, and rosuvastatin (Sadowska et al., 2024). Statin derivatives are the main choices in the treatment of dyslipidemia, widely used and commercially available on the global market (Merćep et al., 2023). Statin derivatives work by inhibiting 3-hydroxy-3-methyl-glutaryl-coenzyme reductase in a competitive and very effective way to reduce the total cholesterol levels, and achieve low density lipoprotein levels, very low density lipoprotein levels, and triglycerides levels, as well as being able to increase high density lipoprotein levels in dyslipidemia patient (Gesto et al., 2020).

Pharmaceutical preparations containing simvastatin, atorvastatin, and rosuvastatin in tablet form are produced by the pharmaceutical industry and are found on the market. Tablets on the market must meet the quality pharmacopoeia requirements to ensure the quality of drugs is suitable for public consumption (Al-Muhsin et al., 2022). Good quality of drug preparations will support the achievement of expected therapeutic effects. Active pharmaceutical ingredient substances are a requirement that must be met to ensure the quality of the marketed drugs (Chaachouay & Zidane, 2024). One of the quality requirements is that the content contained must meet the content requirements as stated in the pharmacopoeia or other standard literature. The importance of quality control and quality assurance has to be supervised and ensure that the drugs produced are in accordance with the intended use (Mashuri et al., 2025).

The World Health Organization pays great attention to the quality, safety, and efficacy of medicines, especially of active ingredients contained in the finished goods (Dey & Nagababu, 2022). In drug manufacture, examination of active substances is

a requirement that must be met to ensure the quality of drug preparations. Good quality drug preparations will support the achievement of expected therapeutic effects (Sampathkumar & Kerwin, 2024). United States Pharmacopoeia includes monographs of simvastatin, atorvastatin, and rosuvastatin tablets by analyzing levels of active substances in tablet preparations using high-performance liquid chromatography (Shulyak et al., 2021).

The utilization of high-performance liquid chromatography methods in analysis has the disadvantage of the high cost of mobile phase, longer preparation time and the longer sample preparation time, uses more expensive solvents, land has longer analysis time (Vempatapu et al., 2024). Development of the Fourier transform infrared spectrophotometric method is an alternative method in pharmaceutical analysis for qualitative and quantitative analysis. The Fourier transform infrared spectrophotometric method uses small amounts of chemicals in sample preparation and could be a low-cost (cheap), environmentally friendly (green), simple (easy), and rapid (fast) analytical method (Nerdy et al., 2021).

Although commercially available statin tablet preparations typically contain only a single active compound, the development of an analytical method capable of simultaneously determining simvastatin, atorvastatin, and rosuvastatin is essential. This approach facilitates the detection of cross-contamination and enhances regulatory compliance. The unified method can also streamline quality control operations and reduce the validation workload. Finally, this single method provides analytical flexibility for both current and future pharmaceutical research and product development. Based on this, this research aims to develop a simple and fast analysis method that can be used to determine levels of three different statin derivatives (simvastatin, atorvastatin, and rosuvastatin) in tablet preparations.

EXPERIMENTAL SECTIONS

Materials and Methods

This research is a descriptive study to determine the levels of simvastatin, atorvastatin, and rosuvastatin in tablet formulations containing a single active pharmaceutical ingredient. The tablet preparations used were marketed tablet preparations with a dose of 20 mg single active pharmaceutical ingredient per tablet. The procedure used in this study is a modification of the research of Nerdy et al, (2023), Al-Shami et al. (2024), and Shadrack et al. (2025). This study consisted of several stages, namely: determination of specific wave number of simvastatin, atorvastatin, and rosuvastatin; determination of linearity, limit of detection, and limit of quantitation of simvastatin, atorvastatin, and rosuvastatin; determination of simvastatin, atorvastatin, and rosuvastatin in tablet preparations; accuracy and precision of simvastatin, atorvastatin, and rosuvastatin.

Materials

The materials used in this study are Simvastatin (Merck), Atorvastatin (Merck), Rosuvastatin (Merck), Chloroform (Merck), Water (Merck), Norpid® 20 mg (Graha Farma), Renapid® 20 mg (Bernofarm), Rechol® 20 mg (Pharos Indonesia), Litorcom® 20 mg (Combiphar), Atofar® 20 mg (Pratapa Nirmala), and Giventor® (Nufarindo).

Tools

The tools used in this study are: Analytical Balance - Cubis 120 (Sartorius), Fourier Transform Infrared Spectrophotometer - Zn Se Cary 630 (Agilent); Absorbance Transmission Module - Dialpath (Agilent), Glassware (Iwaki); Sonicator (Krisbow).

Software

The software used in this study are Micro Lab PC (Agilent), Micro Lab Quant (Agilent), and Statistical Product and Service Solutions (International Business Machines).

Determination of Specific Wave Number of Simvastatin, Atorvastatin, and Rosuvastatin

An amount of 800 mg of simvastatin, 800 mg of atorvastatin, and 800 mg of rosuvastatin was carefully weighed, inserted separately into a 20 mL volumetric flask, added 15 mL chloroform, sonicated until dissolved, diluted with chloroform to the mark line, and shaken until homogeneously mixed (a standard stock solution of 40.0 mg/mL was obtained with each concentration of simvastatin, atorvastatin, and rosuvastatin). An amount of 2.5 mL of each simvastatin, atorvastatin, and rosuvastatin standard stock solution was pipetted, inserted in three separate 20 mL volumetric flasks, diluted with chloroform to the mark line, and shaken until homogeneously mixed (a standard solution containing of simvastatin, atorvastatin, and rosuvastatin with a concentration 5.0 mg/mL in three separate volumetric flasks). The absorption spectrum measurements were carried out on chloroform and separate standard solutions (separate solutions of simvastatin, atorvastatin, and rosuvastatin) by Fourier transform infrared spectrophotometer with 0.1 mm cell in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}. Measurements were made with six replications. The overlap of chloroform absorption spectrum and separate standard solution absorption spectrum was carried out. The specific wavelengths of simvastatin, atorvastatin, and rosuvastatin were determined by Micro Lab PC (Nerdy et al., 2023).

Determination of Linearity, Limit of Detection, and Limit of Quantitation of Simvastatin, Atorvastatin, and Rosuvastatin

An amount of 1.0 mL, 1.5 mL, 2.0 mL, 2.5 mL, 3.0 mL, 3.5 mL, and 4.0 mL of each simvastatin, atorvastatin, and rosuvastatin standard stock solution

Was pipetted, mixed same volume of each simvastatin, atorvastatin, and rosuvastatin standard stock solution in five separate 20 mL volumetric flasks, diluted with chloroform to the mark line, and shaken until homogeneously mixed (a standard solution containing a mixture of simvastatin, atorvastatin, and rosuvastatin with a concentration of 2.0 mg/mL of each compound for the first volumetric flask, 3.0 mg/mL of each compound for the first volumetric flask; 4.0 mg/mL of each compound for the first volumetric flask; 5.0 mg/mL of each compound for the first volumetric flask; 6.0 mg/mL of each compound for the first volumetric flask; 7.0 mg/mL of each compound for the first volumetric flask; 8.0 mg/mL of each compound for the first volumetric flask). The absorption spectrum measurements were carried out on chloroform and mixture standard solutions (various series concentration of simvastatin, atorvastatin, and rosuvastatin) by Fourier transform infrared spectrophotometer with 0.1 mm cell in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}. Measurements were made with six replications. The overlap of chloroform absorption spectrum and mixture standard solutions absorption spectrum was carried out. The regression equation, determination coefficient, and correlation coefficient of simvastatin, atorvastatin, and rosuvastatin were determined by Micro Lab Quant with the height calculation and area calculation by the specific wavelengths of simvastatin, atorvastatin, and rosuvastatin. The height and the area obtained were further calculated to obtain the limit of detection and the limit of quantitation (Shadrack et al., 2025).

Determination of Simvastatin, Atorvastatin, and Rosuvastatin in Tablet Preparations

A total of 20 tablets of simvastatin (3 samples), atorvastatin (2 samples), and rosuvastatin (1 sample) were separately weighed and separately powdered. An amount of powders were separately weighed equivalent to 50 mg of simvastatin, atorvastatin, or rosuvastatin, inserted into a 10 mL volumetric flask, added 5 mL of chloroform, sonicated then diluted with chloroform until the mark line, filtered, removed 3 mL of the first filtrate, and collected the filtrate (concentration of simvastatin, atorvastatin, or rosuvastatin 5.0 mg/mL). The absorption spectrum measurements were carried out on separate sample solutions (separate solutions of simvastatin, atorvastatin, or rosuvastatin) by Fourier transform infrared spectrophotometer with 0.1 mm cell in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}. Measurements were made with six replications. The samples' absorption spectra were recorded. The height, area, concentration, and percentage of simvastatin, atorvastatin, or rosuvastatin were obtained and determined by Micro Lab PC (Nerdy et al., 2023).

Determination of Accuracy and Precision of Simvastatin, Atorvastatin, and Rosuvastatin

Validation of analytical methods developed with accuracy and precision test parameters is done by measuring recovery percentage and relative standard deviation in three specific ranges, namely: 80%, 100%, and 120% (4.0 mg/mL, 5.0 mg/mL, and 6.0 mg/mL). Validation of accuracy parameters and precision parameters in each specific range was done with three replications and used the standard addition method (70% of the samples and 30% of the standard). In the standard addition method, the number of samples is added with the standard. The accuracy parameter with the recovery percentage criterion is expressed by the difference between the two results of the analysis (before and after the addition of the standard) compared to the actual content (the standard added). Precision parameters with relative standard deviation criteria are calculated from a set of recovery percentage values (Shadrack et al., 2025).

Determination of Range and Specificity of Simvastatin, Atorvastatin, and Rosuvastatin

Validation of analytical methods developed with range test parameter is done by analyzing the concentration range of all parameters from the analytical method validation obtained (linearity, limit of detection, limi t of quantitation, accuracy, and precision). The range of the concentration for validation of analytical methods is the narrow concentration range that met all parameters of the analytical method validation. Validation of analytical methods developed with specificity test parameter is done by measuring placebo test. The placebo was prepared by weight and blend tablet placebo in proportions matching a typical tablet formulation contained microcrystalline cellulose as filler or diluent 35.0%, lactose monohydrate as filler or diluent 35.0%, pregelatinized starch as Binder and Disintegrant 12.5%, corn starch as binder and disintegrant 12.5%, silicon dioxide as glidant 2.5%, magnesium stearate as lubricant 2.5%. An amount equivalent to 200 mg as an average of 1 tablet mass, weight 500 mg of pacebo mixture was inserted into a 10 mL volumetric flask, added 5 mL of chloroform, sonicated then diluted with chloroform until the mark line, filtered, removed 3 mL of the first filtrate, and collected the filtrate. The absorption spectrum measurements were carried out on placebo solutions by Fourier transform infrared spectrophotometer with 0.1 mm cell in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}. Measurements were made with six replications. The placebo absorption spectra were recorded. The height, area, concentration, and percentage of placebo were obtained and determined by Micro Lab PC (Al-Shami et al., 2024).

RESULTS AND DISCUSSIONS

The study began with the determination of the spectrum of chloroform solvents in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}. This was followed by the measurement of the spectrum of simvastatin in chloroform solvent with a concentration 5.0 mg/mL in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}; spectrum of atorvastatin in chloroform solvent with a concentration 5.0 mg/mL in the range of wave numbers 4000 cm^{-1} to 650 cm^{-1}, spectrum of rosuvastatin in chloroform solvent with a concentration 5.0 mg/mL in the range of wave numbers 4000 cm^{-1} to 650 cm^{-1}; and spectrum of the mixture of simvastatin, atorvastatin, and rosuvastatin in a chloroform solvent with a concentration of each compound 5.0 mg/mL in the range of wave numbers 4000 cm^{-1} to 650 cm^{-1}, respectively. The spectra resulted from the measurement were processed by Micro Lab PC and can be seen in **Figure 1** for simvastatin, **Figure 2** for atorvastatin, **Figure 3** for rosuvastatin, and **Figure 4** for mixture of simvastatin, atorvastatin, and rosuvastatin.

Measurement of the spectrum of simvastatin in chloroform obtained simvastatin absorption peaks, which showed different in overlay between the spectrum of simvastatin in chloroform against the chloroform absorption spectrum close to the wave number results in the literature of 1712.7 cm^{-1} (Hakiem et al., 2021) with absorption of 0.816 absorbance unit. Measurement of the spectrum of atorvastatin in chloroform obtained atorvastatin absorption peaks, which showed differences in overlay between the spectrum of atorvastatin in chloroform against chloroform absorption spectrum close to the wave number results in the literature, 1660.5 cm^{-1} (Salazar-Barrantes et al., 2025) with absorption of 0.326 absorbance unit. Measurement of the spectrum of rosuvastatin in chloroform obtained rosuvastatin absorption peaks, which showed different in overlay between the spectrum of rosuvastatin in chloroform against chloroform absorption spectrum, close to the wave number results in the literature, 965.4 cm^{-1} (Adel et al., 2023), with absorption of 0.803 absorbance unit.

The absorption spectrum of the mixture of simvastatin, atorvastatin, and rosuvastatin in chloroform shows the same wave number when compared to the wave number and absorption of the absorption spectrum of each absorption spectrum from simvastatin, atorvastatin, and rosuvastatin in chloroform. The results can be seen in **Figure 5**. This proved that simvastatin, atorvastatin and rosuvastatin did not influence each other in the quantitation process. This method is often interfered by the solvent spectrum, so a careful analysis is needed to determine the wave number for the analysis of target substances that are not interfered by the solvent used in the analysis (Pasieczna-Patkowska et al., 2025).

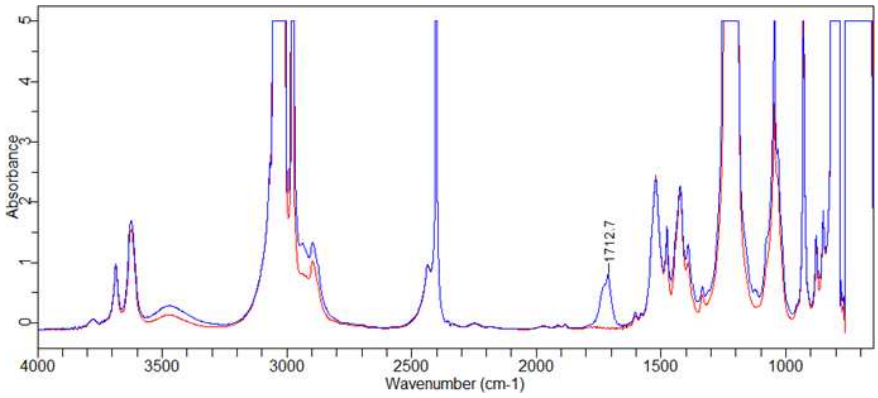

Figure 1. Overlay between the spectrum of chloroform (– red line) against the spectrum of simvastatin in chloroform (– blue line) in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}

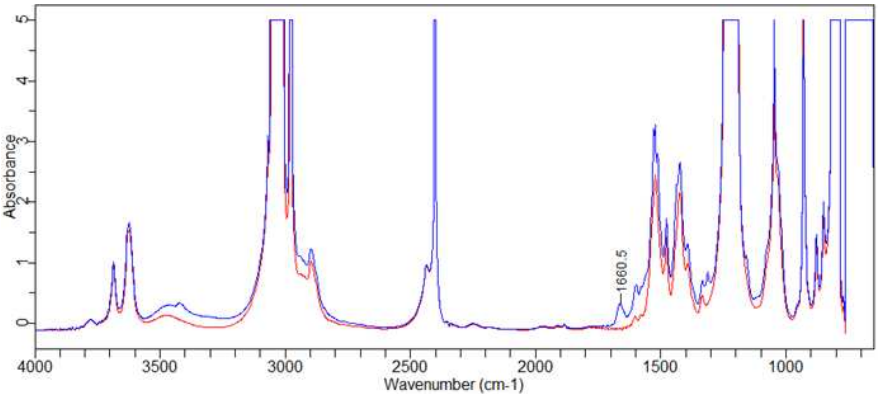

Figure 2. Overlay between the spectrum of chloroform (– red line) against the spectrum of atorvastatin in chloroform (– blue line) in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}

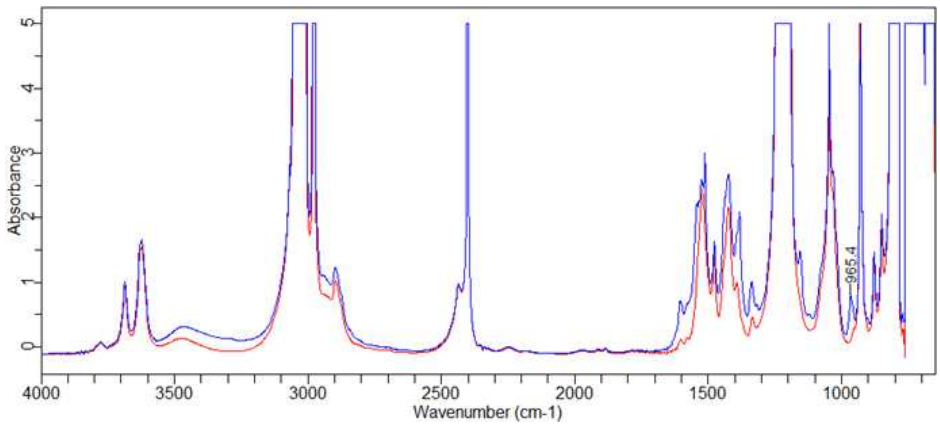

Figure 4. Overlay between the spectrum of chloroform (– red line) against the spectrum of rosuvastatin in chloroform (– blue line) in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}

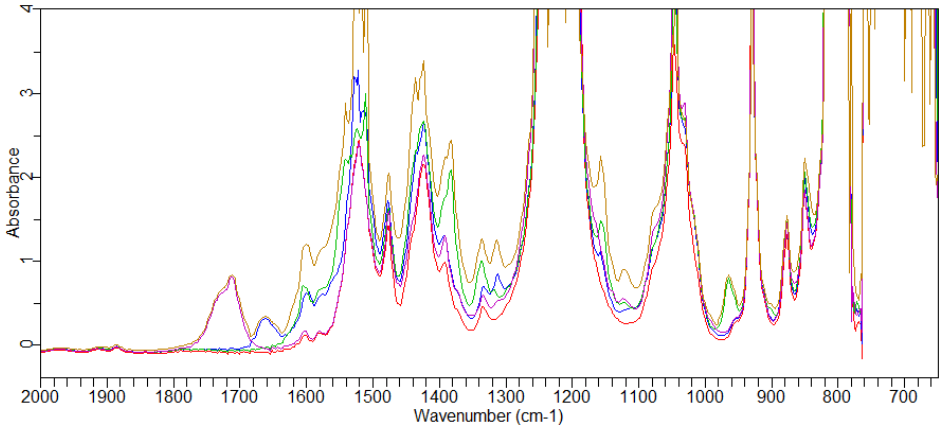

Figure 5. Overlay between the spectrum of chloroform (– red line), simvastatin (– purple line), atorvastatin (– blue line), rosuvastatin (– green line), against mixture of simvastatin, atorvastatin, and rosuvastatin (– orange line) in the wave numbers range between 2000 cm^{-1} to 650 cm^{-1}

The study continued with the determination of linearity of the mixture of simvastatin, atorvastatin, and rosuvastatin in chloroform by measurements of the mixture of simvastatin, atorvastatin, and rosuvastatin in chloroform with concentrations varying from 2.0 mg/mL to 8.0 mg/mL. Measurements were made in the wave numbers range between 4000 cm^{-1} to 650 cm^{-1}. The spectrum obtained from chloroform as a solvent and standard solution containing a mixture of simvastatin, atorvastatin, and rosuvastatin in chloroform was overlaid and determination of the linearity and regression line equations were applied with Micro Lab Quant application using calculations of peak height and peak area. **Figure 6** shows the overlaid spectrum of chloroform as a solvent and standard solution containing a mixture of simvastatin, atorvastatin, and rosuvastatin in chloroform at various concentration ranges (2.0 mg/mL to 8.0 mg/mL).

The results showed that the values of the determination coefficient (R^2) obtained ranged from 0.99826 to 0.99964 with the values of the correlation coefficient (R) obtained ranged from 0.99913 to 0.99982. The determination coefficient values obtained from both peak height and peak area show good results because they were greater than 0.99 (Du et al., 2022; Agberien & Örmeci, 2020), which shows that both peak height and peak area can be used to determine the concentration of simvastatin, atorvastatin, and rosuvastatin. The correlation coefficient values obtained from both peak height and peak area show good results because they were greater than 0.99 (Toropova et al., 2025), which shows that both peak height and peak area have a linear correlation with the concentration of simvastatin, atorvastatin, and rosuvastatin. The results can be seen in **Table 1**.

Determination of simvastatin, atorvastatin, and rosuvastatin levels in tablet preparations was carried out on tablets that are on the market with three simvastatin trademark tablet preparations with a strength of 20 mg per tablet; two atorvastatin trademarks tablet preparations with a strength of 20 mg per tablet; and one rosuvastatin trademark tablet preparation with a strength of 20 mg per tablet. The results of the determination of levels were carried out with six replications. **Table 2** below shows the tabulation results of determination of the levels of active pharmaceutical ingredients in tablet preparations with trademarks containing simvastatin, atorvastatin, and rosuvastatin.

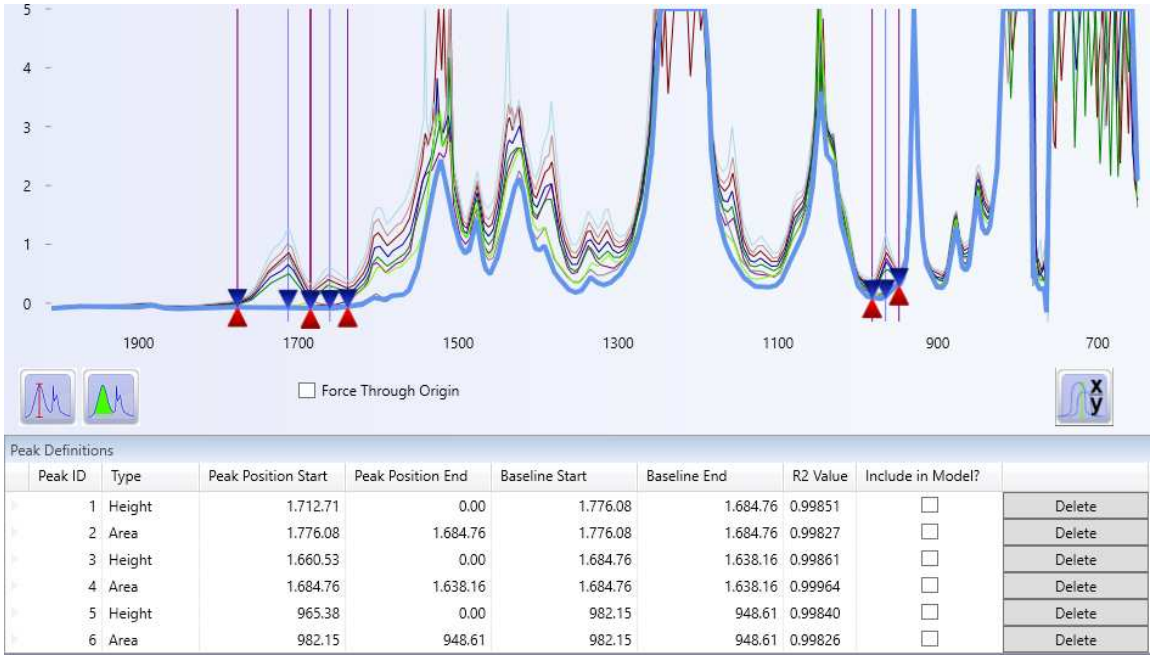

Figure 6. Overlaid spectrum of chloroform as a solvent and standard solution containing a mixture of simvastatin, atorvastatin, and rosuvastatin in chloroform at various concentration ranges (2.0 mg / mL to 8.0 mg / mL)

Table 1. The results of the calculation of slope, intercept, regression equation, determination coefficient, and correlation coefficient from determination of the simvastatin, atorvastatin, and rosuvastatin linearity by peak height and peak area

Number	Compound	Height or Area	Slope	Intercept	Regression Equation	Determination Coefficient (R^2)	Correlation Coefficient (R)
1	Simvastatin	Height	0.16912	0.01850	Y = 0.16912 × X + 0.01850	0.99851	0.99926
2		Area	7.19301	1.62359	Y = 7.19301 × X + 1.62359	0.99827	0.99914
3	Atorvastatin	Height	0.03997	0.03123	Y = 0.03997 × X + 0.03123	0.99861	0.99930
4		Area	0.95064	1.33623	Y = 0.95064 × X + 1.33623	0.99964	0.99982
5	Rosuvastatin	Height	0.10823	0.04294	Y = 0.10823 × X + 0.04294	0.99840	0.99920
6		Area	1.33756	3.06409	Y = 1.33756 × X + 3.06409	0.99826	0.99913

Table 2. The results of determination of the levels of active pharmaceutical ingredients in tablet preparations with trademarks containing simvastatin, atorvastatin, and rosuvastatin

Number	Compound	Sample	Levels of Active Pharmaceutical Ingredients	
			Peak Height	Peak Area
1	Simvastatin	Norpid®	102.83% ± 0.33%	102.75% ± 0.32%
2		Renapid®	101.92% ± 0.29%	101.11% ± 0.30%
3		Rechol®	99.56% ± 0.42%	99.39% ± 0.41%
4	Atorvastatin	Litorcom®	101.81% ± 0.30%	101.99% ± 0.31%
5		Atofar®	100.38% ± 0.55%	100.56% ± 0.57%
6	Rosuvastatin	Giventor®	102.65% ± 0.47%	102.51% ± 0.45%

Table 3. The results of validation with parameters of accuracy, precision, limit of detection, limit of quantitation, and range.

Number	Parameter	Results					
		Simvastatin		Atorvastatin		Rosuvastatin	
		Height	Area	Height	Area	Height	Area
1	Recovery	99.64%	99.47%	99.55%	99.22%	99.80%	99.99%
2	Relative Standard Deviation	0.19%	0.28%	0.13%	0.25%	0.21%	0.31%
3	Limit of Detection	0.14427	0.15561	0.13969	0.07128	0.14972	0.15621
4	Limit of Quantitation	0.43717	0.47154	0.42332	0.21601	0.45370	0.47335
5	Range	4.0 mg/mL to 6.0 mg/mL					

The determination of the levels of simvastatin, atorvastatin, and rosuvastatin on the commercially available trademark tablet preparations calculated by using peak height and peak area. The determination results was compared by t-test and obtained 0.42726 for the p-value. The p-value obtained is not less than than 0.05 indicating that the determination results calculated based on peak height and peak area are not significantly different (Hawi et al., 2025). So that the determination of the levels of simvastatin, atorvastatin, and rosuvastatin can be done by calculation of peak height or peak area calculation. The results obtained in the content determination based on the peak height analysis obtained the results from 99.56% to 102.83%. The results obtained in the content determination based on the peak area analysis obtained the results from 99.39% to 102.75%. These results also indicate that the content of simvastatin, atorvastatin, and rosuvastatin in marketed tablet preparations fulfill the content requirements for active pharmaceutical ingredient assay, which ranges from 90.00% to 110.00% (Pyka-Pająk, 2024).

The analytical method for determination the levels of simvastatin, atorvastatin, and rosuvastatin that is developed must be validated to prove that the analysis method gives valid results. **Table 3** shows the tabulated results of validation with parameters of accuracy, precision, limit of detection, limit of quantitation, and range.

The validation of the analytical method for determining the levels of simvastatin, atorvastatin, and rosuvastatin in tablets with trademark circulating on the market shows results that meet the requirements. Validation of the analytical method with the accuracy parameter by recovery obtained results in the range of 99.22% to 99.99%; the results obtained meet the accuracy test requirements, the recovery is in the range of 98.00% to 102.00% (Amin et al., 2024). Validation of the analytical methods with the precision parameter by relative standard deviation obtained results in the range of 0.13% to 0.31%; the results obtained meet the precision test requirements, the relative standard deviation is not more than 2.00% (Kotani et al., 2024).

Validation of the analytical method with the limit of detection parameter obtained results in the range of 0.07128 mg/mL to 0.15621 mg/mL; the results obtained show good results with a small enough value (32.01 fold to 70.14 fold lower than target concentration 5.0 mg/mL) so that it can be detected with low concentrations. Validation of the analytical method with the limit of quantitation parameter obtained results in the range of 0.21601 mg/mL to 0.47335 mg/mL; the results obtained show satisfactory results with a small enough value so that it can be quantified with low concentrations (10.56 fold to 23.15 fold lower than target concentration 5.0 mg/mL). The value obtained for limit of detection and limit of quantitation showed results that were much lower than the target concentration. These results showed quite satisfactory results (Gegenschatz et al., 2022; Cravotto et al., 2022)

The results of the analytical method validation include linearity at concentrations of 2.0 mg/mL to 8.0 mg/mL; accuracy at concentrations of 4.0 mg/mL to 6.0 mg/mL; precision at concentrations of 4.0 mg/mL to 6.0 mg/mL; detection limit at concentrations of 0.07128 mg/mL to 0.15621 mg/mL; quantitation limit at concentrations of 0.21601 mg/mL to 0.47335 mg/mL. The combination of all parameters from the analytical method validation obtained a range which the concentration of 4.0 mg/mL to 6.0 mg/mL met all parameters of the analytical method validation. In analytical method validation, the range is the span between the highest and lowest concentrations of the analyte in a sample that the method has been shown to measure with accuracy and precision (Blanco-García et al., 2025).

This research contributes to science by developing an analytical method by fourier transform infrared spectrophotometric which is very easy for sample preparations and a very fast sample measurement (Tkachenko & Niedzielski, 2022). However, the spectrophotometric method has a weakness in terms of separation and only background correction (Maia et al., 2023). Simple liquid solvent extraction still allows the matrix of pharmaceutical excipients contained in the tablet preparations extracted together with the active pharmaceutical ingredient

at the extraction stage during sample preparations and also to be analyzed at the measurement stage in infrared spectra. So it is necessary to select a very selective s olvent in quantitative analysis (Kassouf et al, 2024).

Non selective solvent will cause an overestimate to the active pharmaceutical ingredients in the tablet preparations on spectrophotometric analysis (Nikolaychuk, 2023). Placebo analysis is done to ensure that the additional ingredients used in the tablet formulation process do not interfere in the active pharmaceutical ingredient analysis process (Gabel et al., 2023, 2016). So it is very important for the pharmaceutical industry to apply the simvastatin, atorvastatin, and rosuvastatin analysis methods in tablet preparations to conduct a placebo analysis at the initial stage of the analysis. As an alternative to increasing selectivity, solid phase extraction can also be used, followed by validation of analytical methods (Ashwini et al., 2025)

The developed method is able to analyze three anti-dyslipidemia compounds derived from statins, simvastatin, atorvastatin, and rosuvastatin. The developed method has also been validated by providing satisfaction using several analytical method validation parameters, that is, accuracy, precision, linearity, range, limit of detection, limit of quantitation, and specificity. So that this method can be an alternative valid method of reference for the pharmaceutical industry and drug regulatory authorities as a low cost (cheap), environmentally friendly (green), simple (easy), and rapid (fast) analysis method in determination of the levels of simvastatin, atorvastatin, and rosuvastatin in tablet preparations.

CONCLUSIONS

The developed Fourier transform infrared spectrophotometric method has been successfully applied to the analysis of simvastatin, atorvastatin, and rosuvastatin in tablet formulations containing a single active pharmaceutical ingredient. The developed Fourier transform infrared spectrophotometric method was valid and met validation parameters including accuracy, precision, linearity, detection limit, quantitation limit, range, and specificity.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest in this research and this article.

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