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Research Article

Development of UV Spectrophotometric Method and Estimation of Simvastatin in Tablet Formulation

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Abstract

A simple, precise, accurate, and cost-effective UV–visible spectrophotometric method for simvastatin was developed and validated in accordance with ICH Q2 (R1) guidelines. The maximum absorbance wavelength (λmax) of simvastatin was determined to be 238 nm. The range of the calibration curve was between 1-20 µg/mL, and absorbance values were recorded at 238 nm to generate a calibration curve, yielding a correlation coefficient of 0.999. The calculated limit of detection (LOD) and limit of quantitation (LOQ) were 0.11406 µg/mL and 0.34565 µg/mL, respectively. The method demonstrated acceptable accuracy, precision, robustness, and ruggedness when evaluated with quality control standardshe validated method is suitable for the estimation of simvastatin in bulk drug and plant extract samples. The method demonstrated acceptable accuracy, precision, robustness, and ruggedness when evaluated with quality control standards. It was successfully applied for the estimation of simvastatin in bulk drug and commercial tablet formulations.

Keywords: UV-method, Simvastatin, Zocor, Tablet Estimation, Validation.

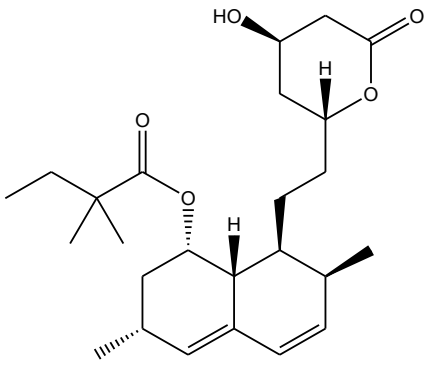
1. INTRODUCTION

Simvastatin, marketed under the brand name Zocor, is a cholesterol-lowering medication that is produced through the chemical modification of compounds obtained from the fermentation of *Aspergillus terreus*. Simvastatin is a member of the statin drug class, which functions as an inhibitor of the enzyme HMG-CoA reductase. The pharmaceutical agent, a synthetic derivative originating from compounds produced by *Aspergillus terreus* fermentation, is primarily utilized for managing dyslipidemia and preventing cardiovascular disorders. Chemically, simvastatin is a lactone prodrug that, upon hydrolysis, undergoes hydrolysis to yield its active β-hydroxyacid metabolite. This active form effectively restricts the activity of HMG-CoA reductase—the crucial enzyme driving the conversion of HMG-CoA to mevalonate, a key early phase in hepatic cholesterol synthesis. [1-6]

By inhibiting the cholesterol biosynthetic pathway, simvastatin decreases endogenous cholesterol production, resulting in reduced low-density lipoprotein (LDL) levels in the circulation. While a variety of analytical approaches, such as HPLC, GC, UPLC-MS/MS, LC-MS/MS, and UV-spectrophotometric techniques, are available for quantifying simvastatin, the study focused on designing a straightforward, reliable, and cost-effective UV spectrophotometric technique for its estimation in both pure substance and tablet formulations. [7-22]

Formula: $C_{25}H_{38}O_5$

Molecular Weight: 418.566 g/mol.



(1S,3R,7S,8S,8aR)-8-{2-[(2R,4R)-4-hydroxy-6-oxooxan-2-yl]ethyl}-3,7-dimethyl-1,2,3,7,8,8a-hexahydronaphthalen-1-yl 2,2-dimethylbutanoate

Figure 1: Chemical structure of Simvastatin

2. MATERIALS AND METHODS

2.1 Chemicals and reagents

The API sample of Simvastatin was procured from Cipla, India. Analytical Grade methanol and water were used. The marketed formulation of simvastatin tablets was purchased from the local market.

2.2 Instrumentation

UV analysis was carried out using a Jasco V 530 UV Double Beam Spectrophotometer and Jasco V 530 Software. Quartz cuvettes (1cm) matched pair quartz cell. Morter and Pestle for crushing the tablets were used. PCi ANALYTICS were used for sonication for dissolving tablet and also centrifuge for separation of dissolved and poorly dissolved powder of tablets.

2.3 Solubility study of the drug

10 mg simvastatin was weighed, and the solubility was observed in 10 ml of water, methanol, 0.1N NaOH, and HCl. By observing the formed solution, the drug is freely soluble in methanol and practically poorly soluble in other solvents. Hence, methanol was selected as a solvent.

2.4.1 Preparation of stock solution

A primary stock solution of Simvastatin was accurately prepared by weighing 10 mg of the analyte and dissolving it in 10 mL of HPLC-grade methanol, yielding a concentration of 1000 µg/mL.

2.4.2 Preparation of standard solution

Subsequently, a 1 mL aliquot of the stock solution was quantitatively transferred into a 10 mL volumetric flask and diluted to volume with a methanol–water mixture (50:50 v/v), resulting in a working standard solution with a final concentration of 100 µg/m.

2.5 Determination of the wavelength of maximum absorption

A 10 µg/mL standard solution was analyzed using UV-Vis spectroscopy across the 200–400 nm range, with a blank as the reference, to determine the wavelength of maximum absorption.

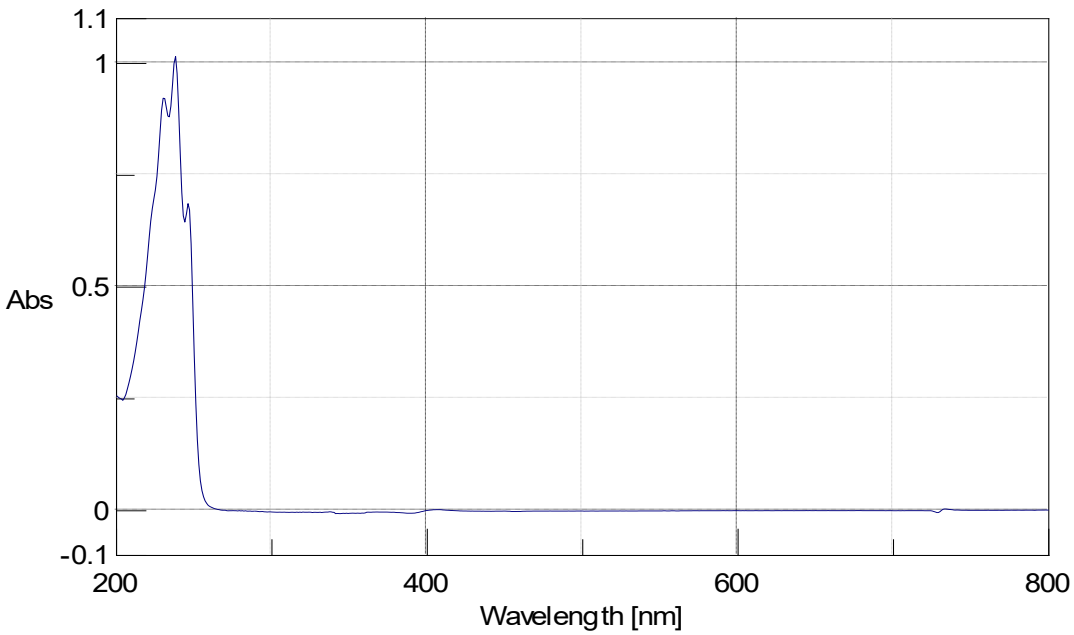


Figure 2: Spectra of Simvastatin at 238nm

The spectra in Figure 2 indicate that the λmax for quantifying Simvastatin is 238.0 nm.

2.6 VALIDATION

The developed UV spectrophotometric method was rigorously validated according to ICH guidelines, evaluating critical parameters such as linearity, precision, accuracy, limit of detection (LOD), and limit of quantification (LOQ), to ensure its suitability for accurate and reliable determination of Simvastatin in both bulk drug substance and tablet dosage forms.

2.6.1 Linearity

The ability of an analytical method to produce results directly proportional to analyte concentration within a specified range. Serial dilutions were carried out from the standard solution to achieve concentrations of 1µg/mL, 2µg/mL, 6µg/mL, 8µg/mL, 12µg/mL, 16µg/mL, and 20µg/mL. The absorbance for each concentration was recorded at a wavelength of 238 nm. A calibration curve was constructed by plotting absorbance values on the Y-axis against their corresponding analyte concentrations on the X-axis, enabling quantification of unknown samples based on the established linear relationship. [23-25]

2.6.2. Precision

The closeness of agreement between repeated measurements of the same standardized sample under specified conditions. The precision of the analytical method was assessed by evaluating both repeatability (intra-day precision) and intermediate precision (inter-day precision) using a standard solution. Six replicate absorbance measurements were recorded from a homogeneous solution under the same experimental conditions. The variability of the results was quantified by calculating the relative standard deviation (%RSD), and the precision was expressed as the %RSD for each level of evaluation.

2.6.3 Accuracy

The accuracy of an analytical method represents the degree of agreement between the measured values and the true value. Accuracy assessment is conducted at three concentration levels—80%, 100%, and 120%—by fortifying the sample with a precisely quantified amount of the reference standard. Each concentration level is analyzed in triplicate to evaluate the method's reliability in producing quantitative results comparable to the actual concentration present. [26-28]

2.6.4 Limit of Detection (LOD)

The Limit of Detection (LOD) is the lowest analyte concentration in a sample that can be reliably differentiated from the background noise. However, it may not be quantified with acceptable accuracy or precision under the specified experimental conditions. Typically, the corresponds to a signal-to-noise ratio of approximately 3:1. In accordance with the International Council for Harmonisation (ICH) guidelines, the LOD can be calculated using the expression:

$$\text{LOD} = \frac{3.3 \times \sigma}{S}$$

where:

- σ represents the standard deviation of the response, determined either from the standard deviation of the regression residuals or from replicate measurements of the blank.
- S denotes the slope of the calibration curve.

2.6.5 Limit of Quantification (LOQ)

The Limit of Quantification (LOQ) is the lowest concentration at which the analyte can be quantified with acceptable levels of accuracy and precision. It is conventionally associated with a signal-to-noise ratio of about 10:1, ensuring the reliability and reproducibility of quantitative results.

LOQ is calculated as:

$$\text{LOQ} = \frac{10 \times \sigma}{S}$$

where σ and *S* carry the same definitions as indicated above.

This approach ensures that both LOD and LOQ are determined based on the calibration curve characteristics and the variability inherent in the analytical method, thereby providing robust sensitivity parameters for method validation. [27,29,30]

2.6.6 Robustness

Robustness of an analytical method denotes its capability to deliver consistent performance despite minor, intentional variations in procedural parameters, thereby confirming its reliability under standard operational conditions. This evaluation assessed robustness by modifying the λmax by ±2 nm for a 10 µg/ml solution, with each assessment performed in triplicate.

2.6.7 Ruggedness

The ruggedness of the analytical method was assessed by performing the analysis on different days, with multiple analysts, and employing reagents and instruments from various manufacturers to evaluate its reproducibility under variable conditions. [27,31,32]

3. RESULTS AND DISCUSSIONS

3.1. Linearity and Range

The obtained calibration curve was evaluated using its correlation coefficient. The absorbance for each concentration was measured at 238 nm. The absorbance of the samples in the range of 1–20 mg/mL was linear, with a correlation coefficient (R2) greater than 0.999, as indicated by the least-squares regression equation y = 0.0555x + 0.0232. The **LOD** and **LOQ** were calculated as **0.11406** mg/mL and **0.34565** mg/mL, respectively. A calibration curve was constructed by plotting absorbance values on the Y-axis against analyte concentrations on the X-axis, enabling quantification of unknown samples based on the established linear relationship.

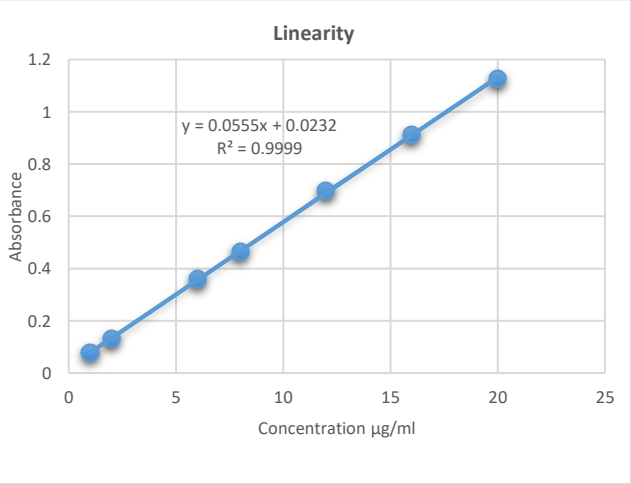


Figure 3: Calibration curve of Simvastatin

Table 1: Calibration curve data of Simvastatin

Sr. No.	Concentration(µg/ml)	Absorbance	Simvastatin	
1	1	0.0784	λmax	238 nm
2	2	0.1381	Con. (µg/ml)	1-20 µg/ml
3	6	0.3606	Correlation	1
4	8	0.4679	Slope	0.0552
5	12	0.6909	Y- intercept	0.0268
6	16	0.9122		
7	20	1.1275		

3.2 Accuracy

Accuracy of the UV–visible spectrophotometric method for simvastatin was assessed using standard addition recovery studies across the full calibration range, ensuring reliability of results at all concentration levels. Recovery experiments were performed at 80%, 100%, and 120% of the nominal concentration. The mean percentage recoveries obtained were 97.7502%, 105.787%, and 100.94%, respectively, with corresponding %RSD values of 2.616, 0.767, and 1.644 (Table 2). All recovery values were within the generally accepted range of 95–105%, confirming that the developed method achieves a high degree of accuracy for the quantitative determination of simvastatin in the tested matrix.

Table 2: Accuracy data of UV method for Simvastatin

Concentration µg/ml	Nominal Concentration	Mean measure Concentration	% Difference	% Recovery	Mean recovery	%RSD
80	1.5	1.45757	2.91993	97.1713	97.7502	2.6164
80	1.5	1.47639	1.62615	98.4259		
80	1.5	1.4648	2.40435	97.6533		
100	10	10.5907	-5.5769	105.907	105.787	0.767
100	10	10.5439	-5.1562	105.439		
100	10	10.6015	-5.6733	106.015		
120	19	19.0218	-0.1102	100.115	100.94	1.644
120	19	19.108	-0.565	100.568		
120	19	19.406	-2.0881	102.137		

3.3 Precision

Precision of the analytical method was assessed at three levels: repeatability, intraday precision, and interday precision. Precision was quantified using standard deviation as a measure of variability. For repeatability, six standard solutions each at 10 µg/ml were prepared, and their absorbance was recorded at 238 nm across three concentration levels. The percentage relative standard deviation (% RSD) was then calculated (Table 3). Intraday precision was evaluated by preparing nine solutions at concentrations of 1.5, 10, and 19 µg/ml, each measured in triplicate.

Interday -

	Morning			**Afternoon**			**Evening**		
Reading	Average	SD	%RSD	Average	SD	%RSD	Average	SD	%RSD
1.5	1.4711	0.0258	1.7609648	1.45237727	0.0275	1.8935256	1.47	0.06	3.79
10	10.563	0.0694	0.6568409	10.597706	0.101	0.9538428	10.58	0.08	0.72
19	18.899	0.2131	1.127785	19.08998	0.1633	0.8558022	19.53	0.1	0.51

Intraday -

Table 3: Precision data (Interday and Intraday) UV method for Simvastatin

	Day 1			Day 2			Day 3		
Reading	Average	SD	%RSD	Average	SD	%RSD	Average	SD	%RSD
1.5	1.444	0.0191	1.32583	1.5004	0.0355	2.36564	1.4596	0.0238	1.63251
10	10.618	0.0581	0.54736	10.494	0.0571	0.54404	10.623	0.0509	0.47939
19	19.145	0.2794	1.45957	19.132	0.3022	1.57971	19.282	0.3816	1.97907

3.4Limit of Detection (LOD) and Limit of Quantification (LOQ)

Limit of Quantitation (LOQ) is the lowest concentration of an analyte that can be quantitatively measured with acceptable accuracy and precision, and it generally corresponds to the lowest point on the calibration curve. For the proposed UV–visible spectrophotometric method, the Limit of Detection (LOD) and Limit of Quantitation (LOQ) were determined to be 0.11406 µg/mL and 0.34565 µg/mL, respectively as shown in Table. The low LOQ indicates that the method has sufficient sensitivity to accurately quantify simvastatin even at trace concentrations in the sample.

Table 4: LOD and LOQ data of UV method for Simvastatin

1	**LOD**	**0.11406395**
2	LOQ	0.34564833

3.5 Robustness

Robustness refers to the ability of an analytical method to maintain its performance despite small, deliberate variations in experimental conditions. This parameter is important because minor, unintentional changes in factors such as solvent composition, buffer strength, or pH can occur during routine analysis and may potentially affect method reliability. For the proposed UV–visible spectrophotometric method, robustness was assessed by varying the solvent composition. Changing the methanol: water ratio from 52:48 to 48:52 produced no significant change in analytical performance, confirming that the method is robust under these tested conditions.

Table 5: Methanol: Water (48:52) ratio data of UV method for Simvastatin

	1.5		10		19	
Sr. no.	LQC	Amount	MQC	Amount	HQC	Amount
1	0.103	1.556313993	0.616	10.3105802	1.1298	19.078
2	0.1064	1.614334471	0.6265	10.4897611	1.117	18.86
3	0.1003	1.510238908	0.6192	10.3651877	1.1104	18.747

Table 6: Methanol: Water (52:48) ratio data of UV method for Simvastatin

	1.5		10		19	
Sr. no.	LQC	Amount	MQC	Amount	HQC	Amount
1	0.102	1.539249147	0.626	10.4812287	1.1163	18.848
2	0.1035	1.564846416	0.6188	10.3583618	1.1149	18.824
3	0.1033	1.561433447	0.6276	10.5085324	1.1188	18.891

3.6 Ruggedness

Ruggedness is defined as the ability of an analytical method to consistently produce accurate and precise results despite deliberate or unintentional variations in external or environmental conditions, such as changes in temperature, instrumentation, analysts, or laboratory location. Methods with high ruggedness are preferred because they remain unaffected by such factors, ensuring reproducibility across different settings. The ruggedness of the proposed UV–visible spectrophotometric method for simvastatin was assessed by analyzing simvastatin dilutions using two different UV–visible spectrophotometers located in separate laboratories. The comparable results obtained from both instruments confirmed that the method is rugged and reliable under varying operational conditions.

Table 7: Ruggedness data of UV method for Simvastatin

Sr. No.	Concentration (µg/mL)	Make and Model of instrument	Conc. (µg/mL)	% RSD
1	10	Jasco, V 530	0.6250932	1.0839
2	10	Perkin Elmer, Lambda 25	0.615933	0.167048

3.7 Assay of tablet formulation

Three tablets each of SIMVOTIN® 20 mg and SIMVOTIN® 10 mg (Sun Pharmaceutical Industries Ltd., India) were accurately weighed and powdered separately. From each batch, an amount of powder equivalent to 10 mg of simvastatin was accurately weighed, finely triturated in a mortar and pestle, and transferred to a beaker containing pure methanol. The mixture was vortex-mixed, sonicated, and centrifuged to obtain a clear supernatant, which was transferred to a 10 mL volumetric flask and diluted to volume with methanol, yielding a stock solution of 1000 µg/mL. From the stock, an aliquot was diluted with methanol: water (50:50, v/v) to obtain a 100 µg/mL intermediate solution, which was further diluted to 10 µg/mL for analysis. The entire procedure was performed separately for the 20 mg and 10 mg tablet formulations, each using three tablets.

$$\text{Percent Assay} = \frac{\text{Amount of API found}}{\text{Amount of API claimed on label}} \times 100$$

Sr. No.	Label claim (mg)	Tablet solution containing Simvastatin(µg/ml)	% Found	Mean % Found	% RSD
T1	20	10	99.3368	99.6742	1.13768523
T2	20	10	101.657		
T3	20	10	99.7731		
T4	10	10	99.4415		
T5	10	10	98.151		
T6	10	10	99.6858		

CONCLUSION

A simple, accurate, and precise UV–Visible spectrophotometric method for the quantitative estimation of Simvastatin was developed and validated in accordance with ICH guidelines. The method exhibited robustness and ruggedness, confirming its reliability for routine analytical determination.

Conflict of Interest: The authors declare no potential conflict of interest concerning the contents, authorship, and/or publication of this article.

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REFERENCES

1. Endo A. A historical perspective on the discovery of statins. Proc Jpn Acad Ser B Phys Biol Sci. 2010;86(5):484 93. https://doi.org/10.2183/pjab.86.484 PMid:20467214 PMCid:PMC3108295

2. Istvan ES, Deisenhofer J. Structural mechanism for statin inhibition of HMG CoA reductase. Science. 2001;292(5519):1160 4. https://doi.org/10.1126/science.1059344 PMid:11349148

3. Plosker GL, McTavish D. Simvastatin: a review of its pharmacology and therapeutic potential in hypercholesterolaemia. Drugs. 1991;42(1):65 89. https://doi.org/10.2165/00003495-199142010-00005 PMid:1718686

4. U.S. National Library of Medicine. Simvastatin [Internet]. StatPearls. Treasure Island (FL): StatPearls Publishing; 2025 [cited 2025 Aug 12]. Available from:

5. Wishart DS, Feunang YD, Guo AC, Lo EJ, Marcu A, Grant JR, et al. DrugBank 5.0: a major update to the DrugBank database for 2018. Nucleic Acids Res. 2018;46(D1):D1074 82. https://doi.org/10.1093/nar/gkx1037 PMid:29126136 PMCid:PMC5753335

6. Sweetman SC, editor. Martindale: The complete drug reference. 37th ed. London: Pharmaceutical Press; 2011.

7. Guzik L, Mrozik W, Kamysz W. Determination of Simvastatin in Pharmaceutical Dosage Forms by Optimized and Validated Method Using HPLC/UV. Croat Chem Acta. 2010;83(4):371-7.

8. Desai MM, Pratima A, Nikalje G. Quality-by-Design Based Development and Validation of Stability Indicating Method by UPLC Method for Impurities of Simvastatin from Drug and Pharmaceutical Dosage Form [Internet]. Vol. 110, Indian Journal of Pharmaceutical Sciences. Available from: www.ijpsonline.com

9. Rajput G, Singh S, Das Kurmi B. Simultaneous estimation of simvastatin and fenofibrate from their combined dosage form by ultraviolet-visible spectroscopy using simultaneous equation method. Pharmaspire [Internet]. 2021;13(1):117-21. Available from: www.isfcppharmaspire.com

10. Dhobale G, Kanawade S, Hande R, Dhobale S, Tare H. Analytical Method Development by Using UV-Spectrophotometer for Estimation of Valsartan in Bulk. INTERNATIONAL JOURNAL OF PHARMACEUTICAL QUALITY ASSURANCE. 2024 Jun 25;15(02):854-60. https://doi.org/10.25258/ijpqa.15.2.49

11. Jemal M, Ouyang Z, Powell ML. Direct-injection LC-MS-MS method for high-throughput simultaneous quantitation of simvastatin and simvastatin acid in human plasma [Internet]. Vol. 23, Journal of Pharmaceutical and Biomedical Analysis. 2000. Available from: www.elsevier.com/locate/jpba https://doi.org/10.1016/S0731-7085(00)00309-5 PMid:10933525

12. Sai Bharath R, Aswini A, Arshiya J, Nikhil Yadav J, Siddartha G, Richards OTRI PM, et al. Development and Validation of UV/Visible Spectrophotometric Method for the Estimation of Simavastatin in Bulk and Pharmaceutical Formulations. Int J Pharm [Internet]. 2017;7(2):138-41. Available from: http://www.pharmascholars.com

13. Maleque M, Hasan MR, Hossen F, Safi S. Development and validation of a simple UV spectrophotometric method for the determination of levofloxacin both in bulk and marketed dosage formulations. J Pharm Anal. 2012;2(6):454-7. https://doi.org/10.1016/j.jpha.2012.06.004 PMid:29403782 PMCid:PMC5760935

14. Sahoo NK, Sahu M, Srinivasa Rao P, Vineela RS, Indira Devi JNV, Sandhya Rani N, et al. Validation of assay indicating method development of simvastatin in bulk and its tablet dosage form by RP-HPLC. J Appl Pharm Sci. 2014;4(1):117-22. https://doi.org/10.7324/JAPS.2014.40120

15. Chavhan V, Reddy K, Ahhirao K. DEVELOPMENT OF UV SPECTROPHOTOMETRIC METHODS AND VALIDATION FOR ESTIMATION OF SIMVASTATIN IN BULK AND TABLET DOSAGE FORM BY ABSORBANCE MAXIMA AND AREA UNDER THE CURVE METHOD. Vol. 55, Journal of Applied Pharmacy. 2014. https://doi.org/10.21065/19204159.6.55

16. Munir A, Ahmad M, Malik MZ, Minhas MU. Analysis of simvastatin using a simple and fast high performance liquid chromatography-ultra violet method: Development, validation and application in solubility studies. Tropical Journal of Pharmaceutical Research. 2014 Jan;13(1):135-9. https://doi.org/10.4314/tjpr.v13i1.19

17. Sai Bharath R, Aswini A, Arshiya J, Nikhil Yadav J, Siddartha G, Richards OTRI PM, et al. Development and Validation of UV/Visible Spectrophotometric Method for the Estimation of Simavastatin in Bulk and Pharmaceutical Formulations. Int J Pharm [Internet]. 2017;7(2):138-41. Available from: http://www.pharmascholars.com

18. Birari AE. Development and Validation of UV-Spectrophotometric Method for Estimation of Simvastatin in Bulk and Solid Dosage Form.

19. Wang L, Asgharnejad M. Second-derivative UV spectrometric determination of simvastatin in its tablet dosage form [Internet]. Vol. 21, Journal of Pharmaceutical and Biomedical Analysis. 2000. Available from: www.elsevier.com/locate/jpba https://doi.org/10.1016/S0731-7085(99)00231-9 PMid:10708408

20. Dey S, Pharm M, Kumar Pradhan P, Upadhayay UM, Patel C, Lad B. Method Devlopment and Validation of Simvastatin by UV Spectrophotometric Method. J Pharm Res [Internet]. 2012;5(12):5380-2. Available from: https://www.researchgate.net/publication/288567476

21. Chavhan V, Ghante M. Stability Indicating UV Spectrophotometric Method Development And Validation Of Simvastatin In Bulk And Tablet Dosage Form. Journal of Applied Pharmacy. 2014;235.

22. Dhole SM, Yeole MP. First derivative UV-spectrophotometric method for simultaneous determination of simvastatin and ezetimibe in tablet dosage form. Scholars Research Library Der Pharmacia Lettre [Internet]. 2015;7(3):124-8. Available from: www.scholarsresearchlibrary.com

23. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q2(R1): Validation of Analytical Procedures: Text and Methodology. Geneva: ICH; 2005.

24. de Andrade MC, de Souza PL, Teixeira HL. Validation of a UV-spectrophotometric analytical method for determining a drug substance by linear regression analysis. Braz J Pharm Sci. 2019;55:e17707.

25. Patel N, Patel B, Patel M. Development and validation of UV spectrophotometric method for quantitative estimation of pharmaceutical compounds. Int J Pharm Sci Res. 2013;4(6):2318-23.

26. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q2(R1): Validation of analytical procedures: text and methodology. Geneva: ICH; 2005.

27. Miller JN, Miller JC. Statistics and chemometrics for analytical chemistry. 6th ed. Harlow (UK): Pearson Education; 2010.

28. Ermer J, Miller JH. Method validation in pharmaceutical analysis: a guide to best practice. 2nd ed. Weinheim: Wiley-VCH; 2014. https://doi.org/10.1002/9783527672202

29. Shrivastava A, Gupta VB. Methods for the determination of limit of detection and limit of quantitation of the analytical methods. Chron Young Sci. 2011;2(1):21 5. https://doi.org/10.4103/2229-5186.79345

30. Long GL, Winefordner JD. Limit of detection: A closer look at the IUPAC definition. Anal Chem. 1983;55(7):712A 724A. https://doi.org/10.1021/ac00258a001

31. Ermer J. Validation in pharmaceutical analysis. Part I: An integrated approach. J Pharm Biomed Anal. 2001;24(5 6):755 67. https://doi.org/10.1016/S0731-7085(00)00530-6 PMid:11248468

32. Blessy M, Patel RD, Prajapati PN, Agrawal YK. Development of forced degradation and stability indicating studies of drugs-A review. J Pharm Anal. 2014;4(3):159 65. https://doi.org/10.1016/j.jpha.2013.09.003 PMid:29403878 PMCid:PMC5761119