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Research Article

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" ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF MAVACAMTEN API BY RP-HPLC"

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ABSTRACT:
The quantitative analysis of Mavacamten in bulk form was performed by developing and validating a simple, rapid, precise, and stability-indicating RP-HPLC method. The method worked well for chromatographic separation, with great peak resolution and the right amount of time for retention. Validation testing confirmed that the method is reliable, precise, and suitable for standard quality control analysis of Mavacamten in bulk medicine samples. A reverse-phase high-performance liquid chromatography (RP-HPLC) method was established for the analysis of Mavacamten utilizing a C18 column, with a mobile phase of acetonitrile and water in a 90:10 ratio, a flow rate of 1.0 mL/min, and detection at 268 nm. The approach demonstrated a retention time of approximately 5.3 minutes with methanol utilized as the diluent for sample processing. The system suitability metrics, including theoretical plates, tailing factor, and %RSD, were within acceptable limits. The method was verified in accordance with ICH recommendations for specificity, linearity (2–12 µg/mL), accuracy, robustness, limit of detection (LOD), and limit of quantification (LOQ). The ICH guidelines were used to check the RP-HPLC method for Mavacamten. Specificity testing showed that the blank did not affect the drug's retention time. Precision investigations (system, technique, and intermediate precision) showed %RSD values around 2%, which means that the results were quite consistent. The method showed linearity between 2 and 12 ppm with $r^2 = 0.9988$. Robustness tests showed that the method was not influenced by small changes in flow rate and injection volume. The limits of detection (LOD) and quantification (LOQ) were found to be 0.24 ppm and 0.72 ppm, respectively, which shows that the method is very sensitive.

KEYWORDS
HPLC method development, Sotagliflozin.

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1. INTRODUCTION -

A distinctive, straightforward, sensitive, and reproducible reverse-phase high-performance liquid chromatography (RP-HPLC) method was established and validated for the detection of Mavacamten in bulk medicinal compounds and pharmaceutical formulations. Chromatographic separation was executed utilizing a C18 reverse-phase column under optimal conditions. An optimal mixture of organic solvent and aqueous buffer was provided at an ideal flow rate in isocratic mode as the mobile phase. Detection was performed using a UV detector at a designated wavelength that provided suitable sensitivity for both analytes. The novel methodology exhibited adequate separation with clearly defined, symmetrical peaks and appropriate retention times for Mavacamten. The technique validation approach adhered to the criteria of the International Council for Harmonization (ICH), encompassing aspects such as system suitability, specificity, linearity, accuracy, robustness, limit of detection (LOD), and limit of quantification (LOQ). The method demonstrated remarkable linearity over the evaluated concentration range, with correlation coefficients (r^2) exceeding 0.999 for both pharmaceuticals. Recovery studies conducted at multiple concentration levels assessed accuracy, with results falling within acceptable limits, hence confirming the method's reliability. Precision studies, encompassing intra-day and inter-day assessments, demonstrated little percentage relative standard deviation (%RSD), signifying robust repeatability and reproducibility. The LOD and LOQ results confirmed the approach's sensitivity. Research on resilience indicated that minor deliberate alterations in chromatographic parameters did not significantly affect analytical performance. Research on specificity confirmed the absence of influence from solvents, excipients, or degradation products.

The validated RP-HPLC method is cost-effective, rapid, accurate, and precise, rendering it appropriate for routine quality control assessments and stability studies of pharmaceutical formulations, including Mavacamten. **[1-3]**

To treat patients with obstructive hypertrophic cardiomyopathy (HCM), the US Food and Drug Administration (FDA) approved Mavacamten, a unique, first-in-class oral drug that acts as an allosteric modulator of cardiac myosin ATPase. With the goal of enhancing functional ability and reducing symptoms, this drug is now approved for the treatment of individuals with syptomatic heart failure categorized as New York Heart Association (NYHA) class II and III secondary to obstructive HCM.

Mutations in cardiac sarcomere-related genes, such as myosin-binding protein C and β-myosin heavy chain, cause left ventricular hypertrophy in HCM, a prevalent heritable heart condition. In order to treat left ventricular outflow tract (LVOT) obstruction in HCM, Mavacamten targets the underlying myofibrillar disarray and aberrant mitral apparatus. Mavacamten is a new medication used to treat symptomatic individuals with heart failure due to obstructive HCM. This activity focuses on the drug's indications, mechanism of action, side effects, and monitoring regimen. This activity additionally goes over the pharmacokinetics, clinical toxicity, and FDA-issued box warnings of mavacamten, all of which are critical for physicians to comprehend in order to maximize patient care and guarantee the medicine is used safely and effectively.**[4-5]**

Mavacamten is recommended to improve symptoms and functional capacity in persons with symptomatic heart failure who are categorized as New York Heart Association (NYHA) classes II and III due to obstructive HCM. Following the release of the phase III pivotal clinical research EXPLORER-HCM (Evaluate Mavacamten in Adults with Symptomatic Obstructive Hypertrophic Cardiomyopathy), the medication was approved by the US Food and Drug Administration (FDA) in 2022. Obstructive HCM was defined in the EXPLORER study as unexplained left ventricular hypertrophy with a peak LVOT gradient of at least 50 mm Hg at rest

and a left ventricular wall thickness of 15 mm or more. Every patient was 18 years of age or older and had a left ventricular ejection fraction (LVEF) of at least 55%.**[1]** Patients receiving monotherapy with disopyramide or ranolazine, as well as those receiving dual therapy with a calcium channel blocker and a β-blocker, were not included. We excluded patients with known storage or infiltrative illnesses that resulted in left ventricular hypertrophy. Mavacamten was linked to improved NYHA heart failure symptom categorization, improved exercise performance, and a lower resting and post-exercise LVOT gradient after 62 weeks of treatment.

Furthermore, 57% of patients in the mavacamten group experienced a post-exercise LVOT gradient of less than 30 mm Hg, which is 50% greater than the reduction in the placebo group. Additionally, the functional class was reduced by 34% more in the mavacamten group than in the placebo group. Additionally, the use of mavacamten in patients with obstructive HCM was linked to notable improvements in quality of life as determined by a number of health-related quality of life indices, such as the Hypertrophic Cardiomyopathy Symptom Questionnaire Shortness of Breath and the Kansas City Cardiomyopathy Questionnaire Overall Summary Score. **[5]**

After 30 weeks of treatment, mavacamten is linked to absolute decreases in the intracellular myocardial mass index, although there are no alterations in the myocardial contractile fraction or fibrosis, according to cardiac magnetic resonance imaging analysis. **[6]** The long-term net health benefits of mavacamten in individuals with obstructive HCM have been assessed statistically using a Markov model. Compared to current treatment modalities for obstructive HCM, these results imply that mavacamten medication is linked to an incremental increase in years of life and years spent in NYHA functional class I. **[7]**

Mavacamten has also been suggested as a treatment for nonobstructive HCM. The safety and effectiveness of mavacamten in this patient subgroup were investigated in the MAVERICK-HCM study (Mavacamten in Adults with Symptomatic Nonobstructive Hypertrophic Cardiomyopathy). Mavacamten therapy was linked to a significant decrease in myocardial wall stress indicators, including cardiac troponin I and N-terminal pro-B-type natriuretic peptide, in this phase II research. However, the analysis's short treatment duration and dose-finding design made it impossible to evaluate clinically meaningful variations in quality of life or symptoms when compared to a placebo. **[8]**

Mavacamten

In addition to being sold under the Camzyos brand, Mavacamten was also known by a number of other names throughout its development, such as HCM 1, MAVA–Bristol Myers Squibb/MyoKardia, MYK-461, and SAR-439152. Prior to regulatory approval, these designations were based on its joint development history and experimental code names. Pharmacologically speaking, mavacamten is classified under heart failure treatments and is a member of the cardiovascular therapy class. Chemically, it is categorized as a tiny molecule based on pyrimidinone and an ethylamine derivative. Targeted intracellular activity within cardiac muscle cells and oral delivery are made possible by its small-molecule structure.

The specific inhibition of cardiac myosin is the basis for mavacamten's mode of action. By regulating the activity of cardiac myosin ATPase, it inhibits cardiac myosin and lessens the development of excessive actin–myosin cross-bridges. In patients with hypertrophic cardiomyopathy, this results in less myocardial hypercontractility, better diastolic relaxation, and less blockage of the left ventricular outflow tract (LVOT). Instead of just treating the symptoms of obstructive hypertrophic cardiomyopathy, mavacamten targets the fundamental pathophysiology of the condition **[9-15].**

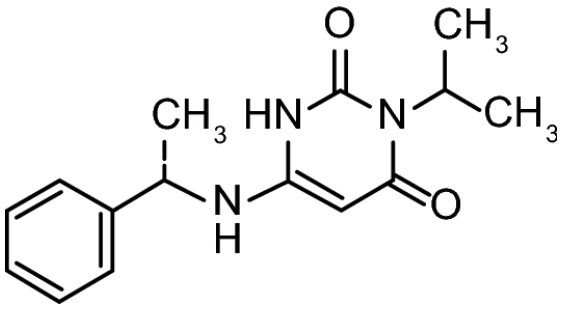

Figure 1- 2D structure of Mavacamten

2.MATERIALS AND METHODS

2.1 Materials

Chemicals

All solvents and diluents used for this method are HPLC grade.

All solvents and other chemicals are from Solanki Enterprises.

- Methanol – HPLC grade
- Acetonitrile - HPLC grade
- Water- HPLC grade
- Mavacamten (Procedure standard)-

Requirements

Essential equipment and supplies for the validation investigation included a mobile phase filtration machine and an analytical balance. The HPLC system employed Jasco ChromNAV 2.0 chromatography software, a Jasco 4600 Separation Module, and a Jasco UV detector. Validation studies were performed using the standard and test samples.

2.2 Methods

Standard Test Procedure: [16-18]

Mobile Phase Selection:

Different combinations of solvent systems according to nature of drug and extensive literature survey were tried in order to determine the best conditions for the effective separation and optimization of sample.

The mobile phase consisting of

Solvent A – Acetonitrile (90%)

Solvent B – Water (10%)

Solvent C – NA (_____%)

Solvent D – NA (_____%)

Requisites:

Mobile Phase (HPLC grade)

Chromatographic condition:

Column : Finepack Jasco 5µ (4.6 X 250 mm)

Flow rate : 1.0 mL/min.

Column temp : 30°C ± 5°C

Sample temp : 25° C ± 5°C

Injection volume : 20 µl

Detector : UV at 268 nm

Run time : 10 minutes

Retention time : About Approx. 5.3 minutes for Mavacamten.

Diluent: Methanol (100%) (Diluent)

Preparation of test solution:

About 10mg of Mavacamten was accurately weighed and transferred into 10 mL volumetric flask. Diluent was added and then sonicated in ultrasonic water bath for 10 minutes. The solution was cooled and volume was made up to the mark with diluent. Then filtered through 0.45 µ syringe filter. Resulting solution was used as test solution.

Standard solution was made by same procedure as mentioned above.

System suitability: [19]

Standard solution in five replicate and test solution in duplicate was injected. System suitability parameters was calculated from standard chromatogram mentioned below.

Theoretical plates for analyte peak

: NLT 2000

Tailing factor for analyte peak

: NMT 2.0

% RSD for replicate injections of standard

: NMT 2.0

Method validation- [20]

Validation in accordance with ICH Q2 criteria. The purity of the analyte peak in standard and

sample solutions, along with the absence of interference reactions at the analyte retention time in blank and placebo chromatograms, indicated specificity. Six concentration levels were employed to assess linearity throughout a range of 2–12 µg/mL; calibration plots of peak area versus concentration yielded a correlation coefficient of no less than 0.95. The precision results later corroborated the development of the validated analytical range within this interval. The percent RSD limitations for peak areas and assay results did not exceed 2.0%. Precision encompassed system precision (six injections of the standard), method precision (six independent sample preparations), and intermediate precision (across different days, analysts, and equipment as applicable). Intentionally adjusting the flow rate to 1 mL/min and altering the organic component of the mobile phase by ±2% (absolute) relative to the optimal 90:10 composition facilitated the assessment of method robustness; system suitability and assay values were required to remain within established limits under these variations. The ICH slope-and-standard-deviation method was employed to estimate the limit of detection and limit of quantification, hence determining sensitivity. The determined LOD and LOQ values were, corresponding to signal-to-noise ratios of around 3 and 10.

Table 1- Validation Parameters

Parameters	**For Assay**
Specificity	√
Linearity	√
Precision	
System Precision	√
Method Precision	√
Intermediate Precision	√
Robustness	
Wavelength	√
Flow rate	√
Mobile phase	√
LOD	√
LOQ	√

Note: √ - Applicable

3. RESULT

3.1 Specificity

The specificity of the method for Assay is demonstrated by injecting following solutions into the HPLC system.

- Diluent as a blank
- Test Solution

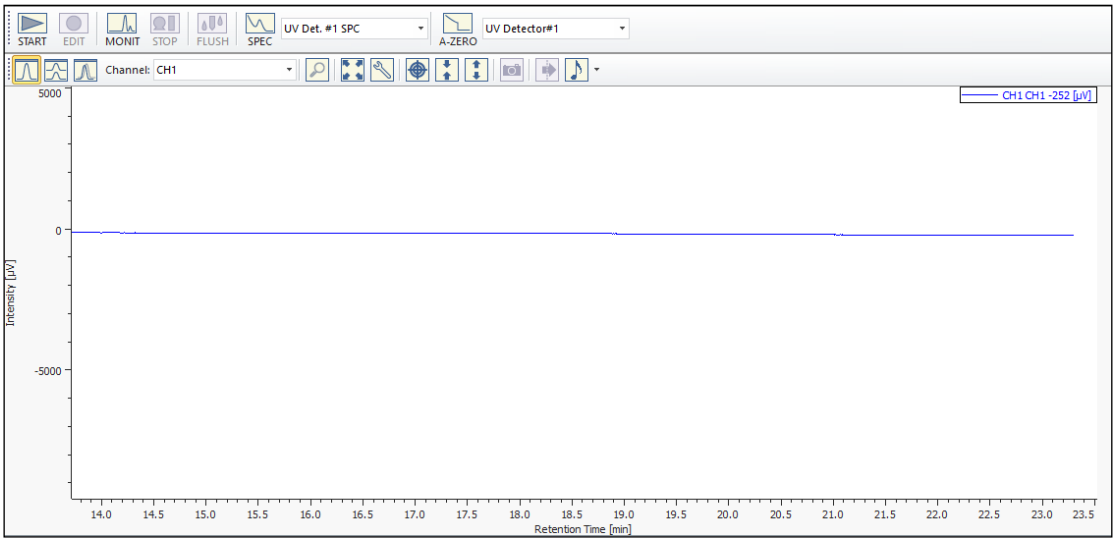

Figure 2- HPLC chromatogram of Blank solution

Table 1- Specificity of Sample

Sr. No.	Sample name	Analyte name	Purity flag	Specificity
1.	Mavacamten	Mavacamten	No	Specific

Results and evaluation:

By comparing the chromatograms of the Blank solution, Standard solution and Test solution the following evaluations were made.

- No peak was co-eluted with analyte peak from blank solution.
- No interfering peak was observed from blank at the retention time of Sample
- No purity flag was observed for sample from test solution and standard solution.

The method is considered to be specific as per the above mentioned observations.

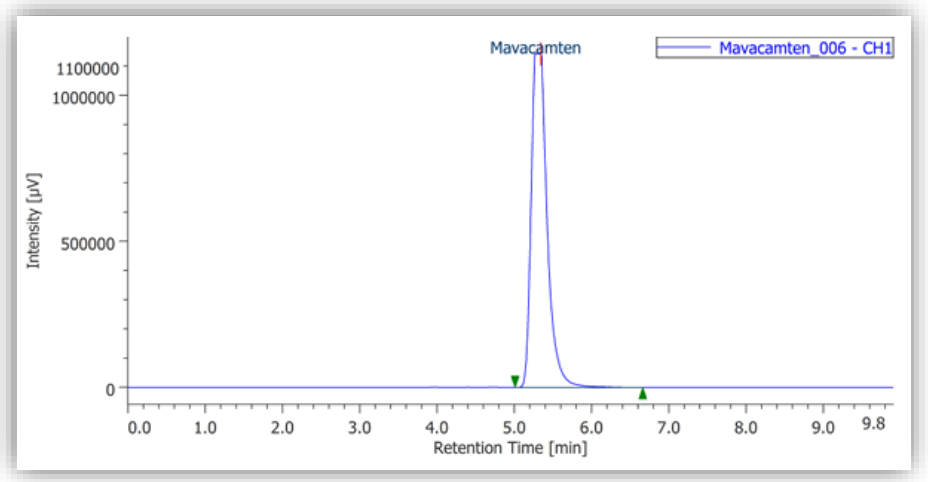

Figure 3- Trail peak of mavacamten

Where,

Mobile phase- 70:30 (Acetonitrile : Water)

Flow rate- 1.2 ml/min

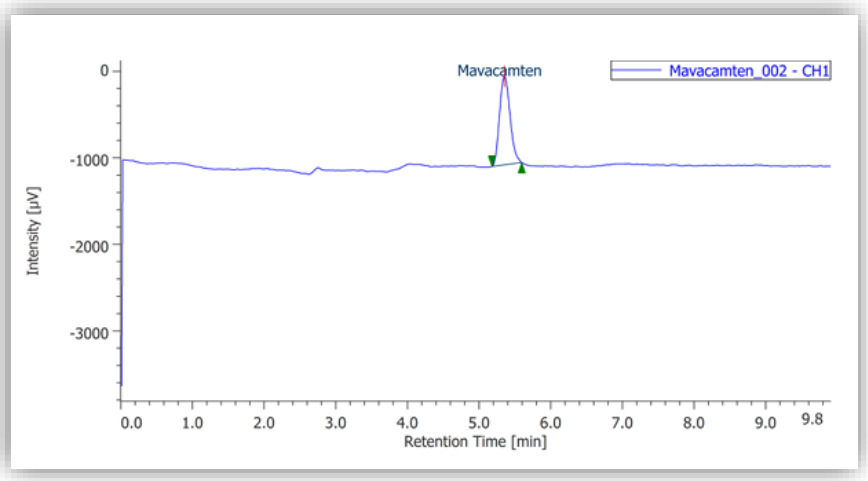

Figure 4- Trail peak of mavacamten

Where,

Mobile phase- 70:30 (Acetonitrile : Water)

Flow rate- 1 ml/min

3.2 System precision

System precision was evaluated from 6 replicate injections of standard as per proposed method. The Peak area, average and % RSD was calculated and tabulated in the Table 4.

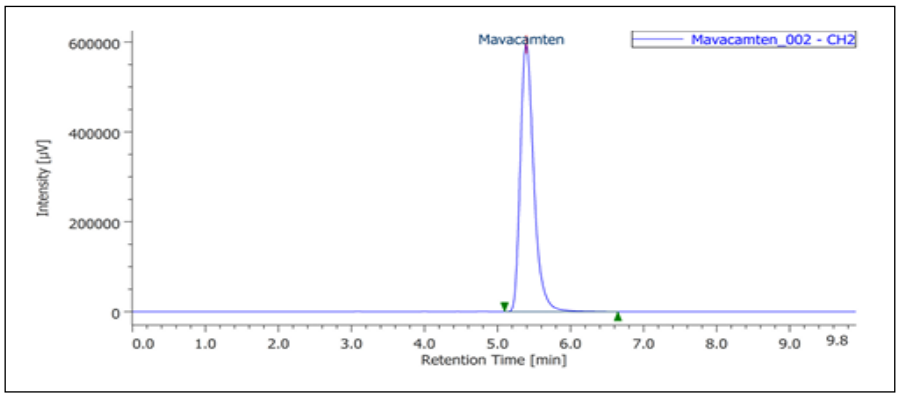

Figure 5- System Precision 1

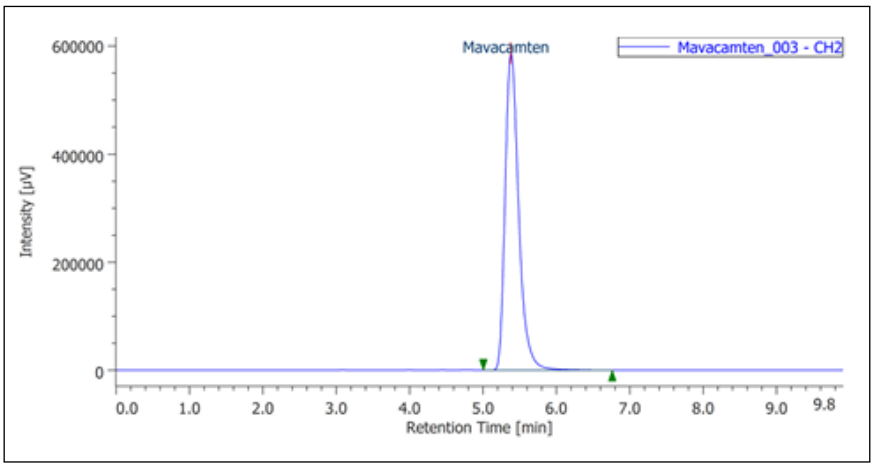

Figure 6- System Precision 2

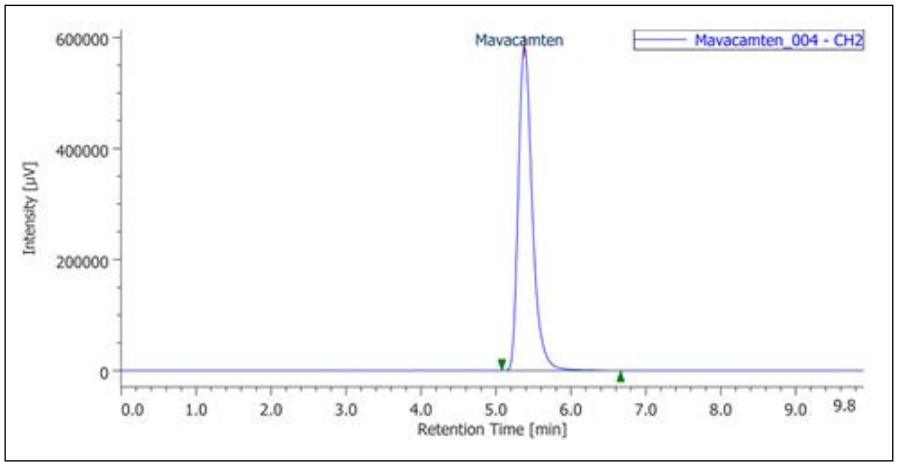

Figure 7- System Precision 3

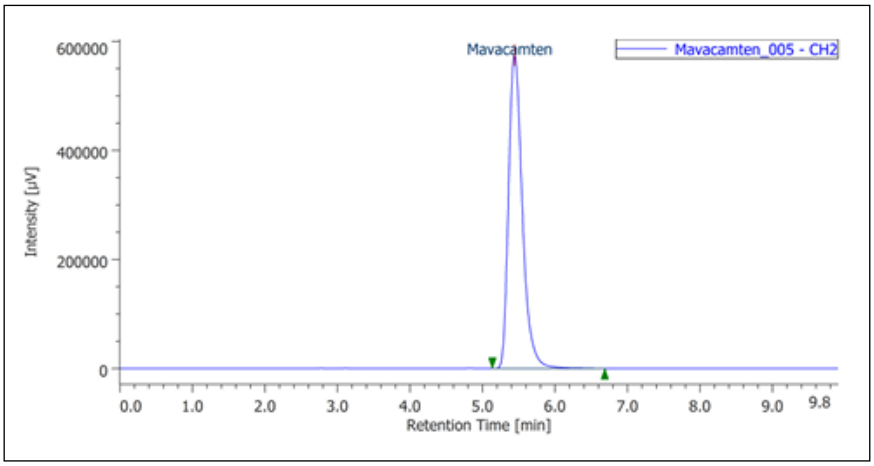

Figure 8- System Precision 4

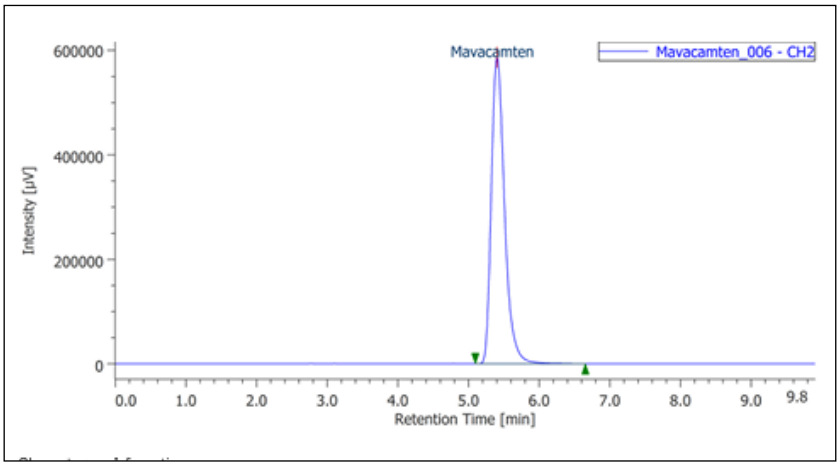

Figure 9- System Precision 5

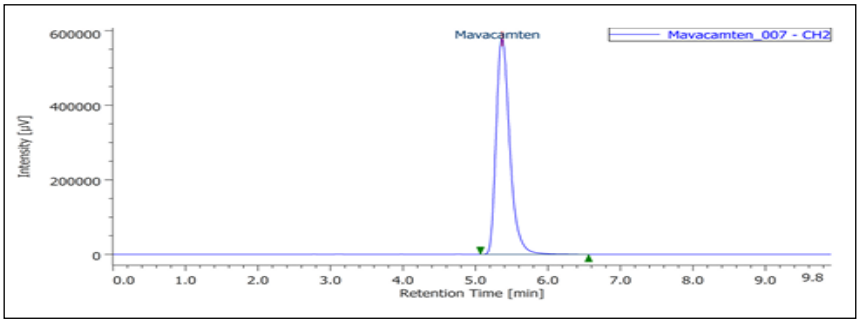

Figure 10- System Precision 6

Table 4: System Precision of Mavacamten

Inject. No	Peak Area of Mavacamten
1	7646893
2	7547770
3	7596334
4	7615681
5	7655288
6	7580655
Mean	7607103.5
% RSD	0.536%

Acceptance Criteria:

The relative standard deviation should be within the following limits % RSD for Area of Mavacamten < 2.0%,

Results and evaluation:

The % RSD observed within acceptable limit indicates the precision of the system.

3.3 Method precision

The six test solutions were prepared separately. Each was analyzed as per proposed procedure. The % assay, average and % RSD was calculated and tabulated in the Table 5.

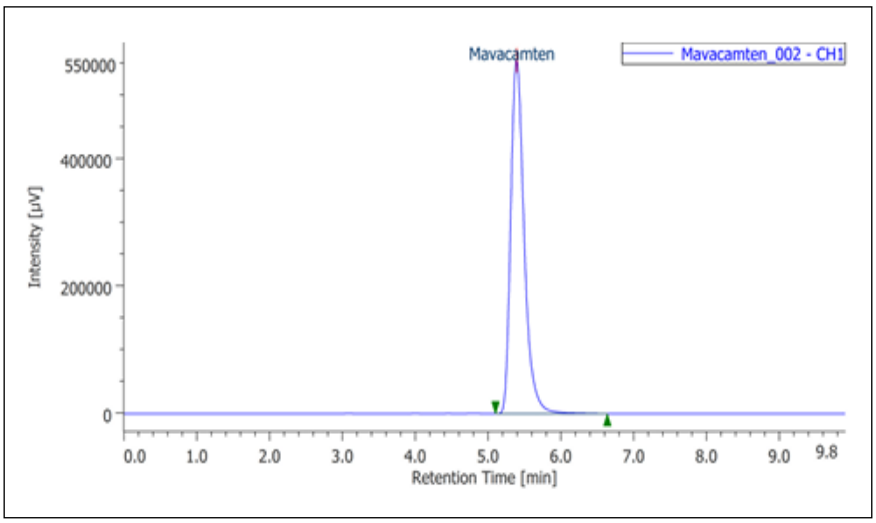

Figure 11- Method Precision 1

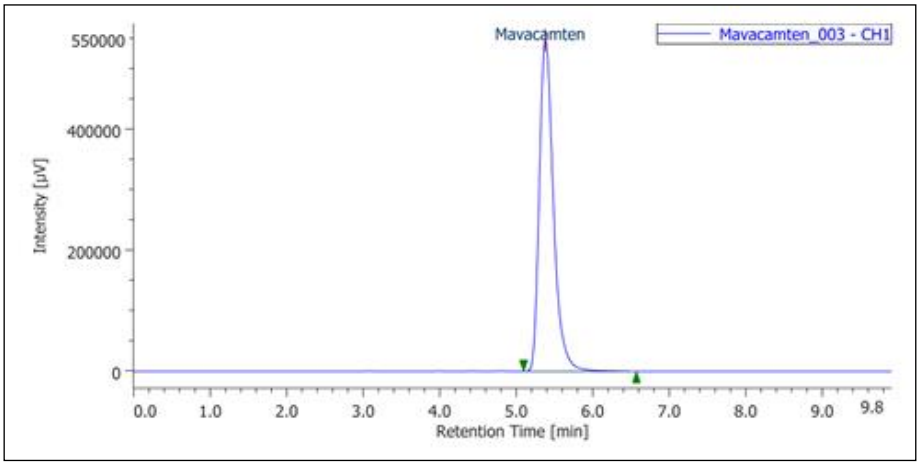

Figure 12- Method Precision 2

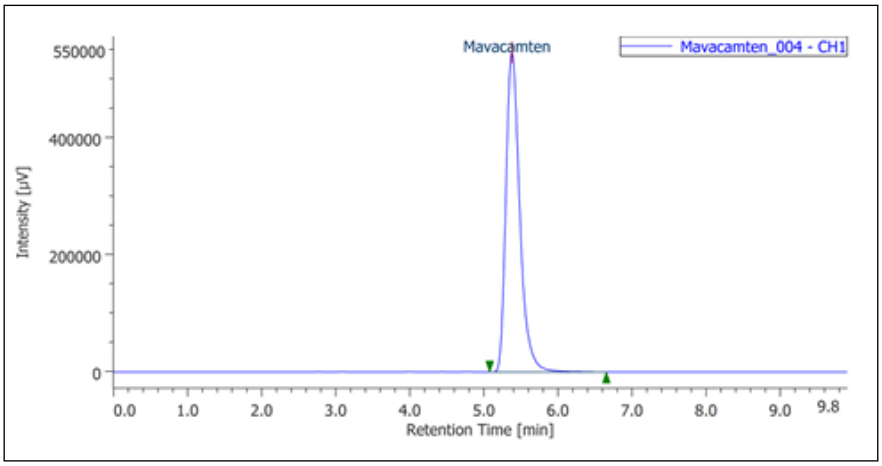

Figure 13- Method Precision 3

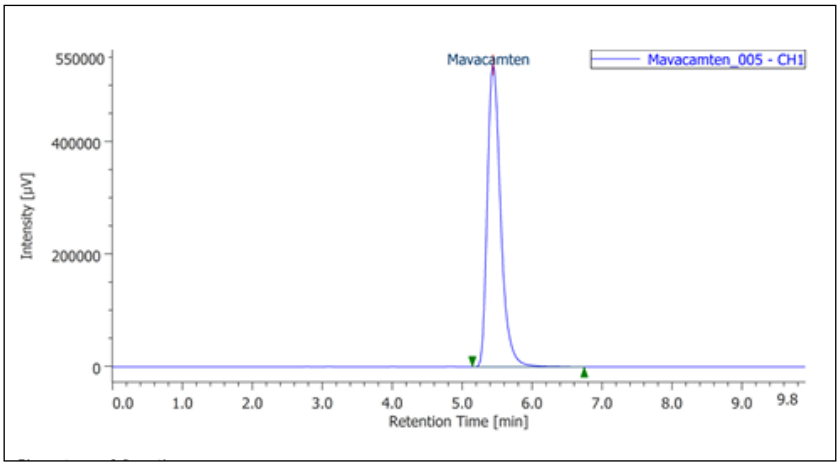

Figure 14- Method Precision 4

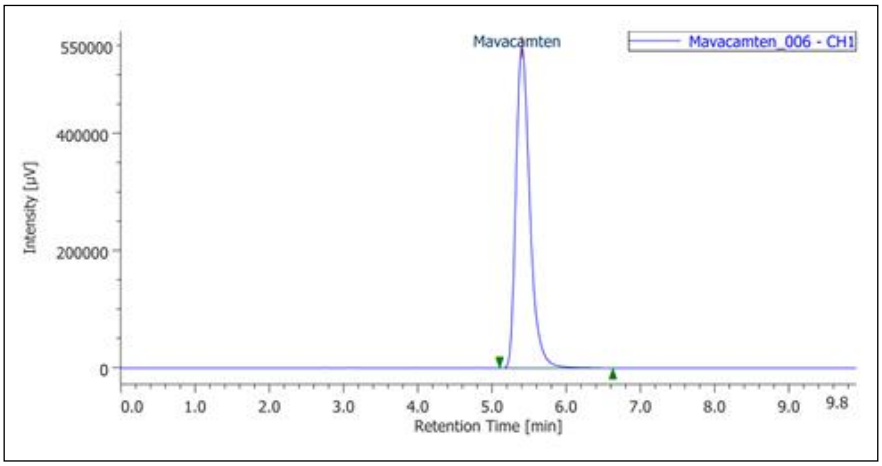

Figure 15- Method Precision 5

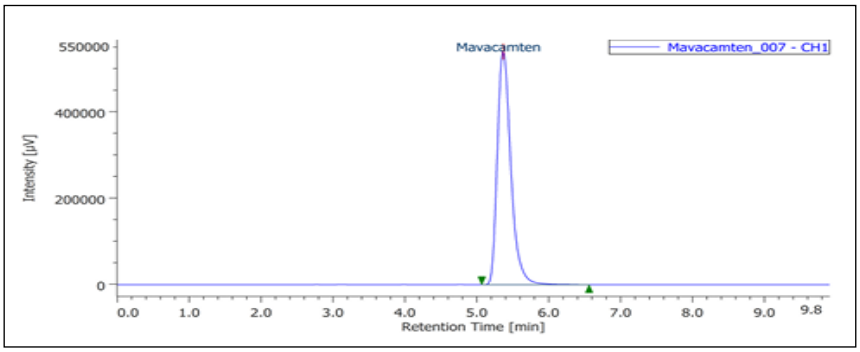

Figure 16- Method Precision 6

Table 2- Method Precision of Mavacamten

Sample No.	% Assay of Sample
1	93.53
2	93.50
3	93.52
4	93.54
5	93.52
6	93.53
Mean	93.523
% RSD	0.015%

Acceptance Criteria:

The relative standard deviation should be within the following limits

% RSD for Assay of Sample < 2.0%,

Results and evaluation:

The % RSD was observed within the limit indicates that the method has an acceptable level of precision.

3.4 Intermediate precision-

The six test solutions were prepared separately. Each was analyzed as per proposed procedure (**analyzed in morning, afternoon and evening i.e. intraday precision and today, tomorrow and day after tomorrow i.e. interday precision**). The % assay, average and % RSD was calculated and tabulated in the Table 6.

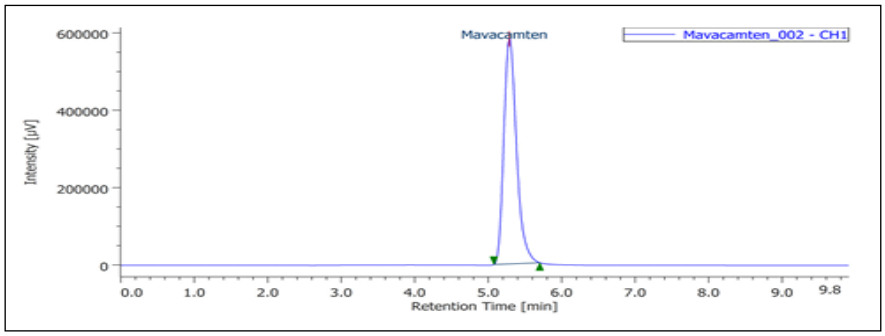

Figure 17- Intermediate Precision (Intraday Morning) 1

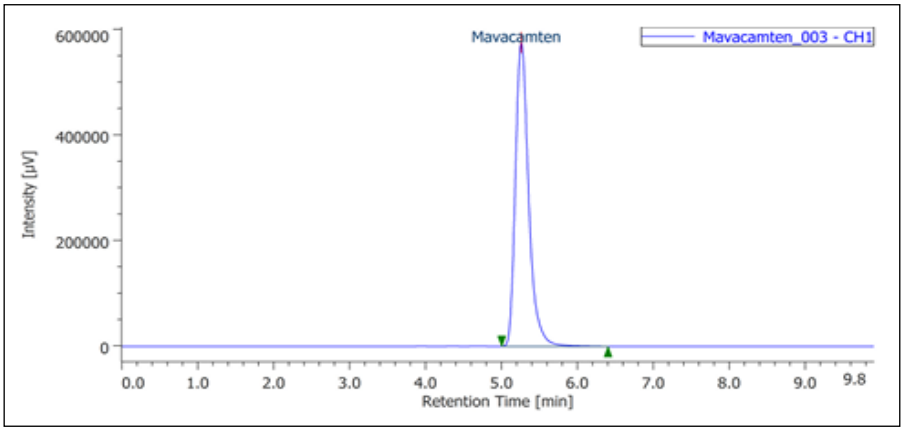

Figure 18- Intermediate Precision (Intraday Morning) 2

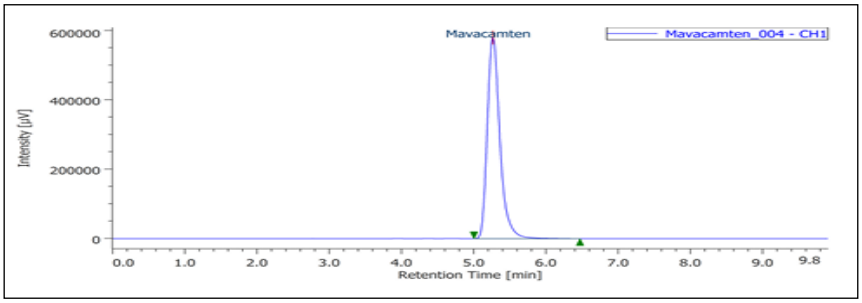

Figure 19- Intermediate Precision (Intraday Morning) 3

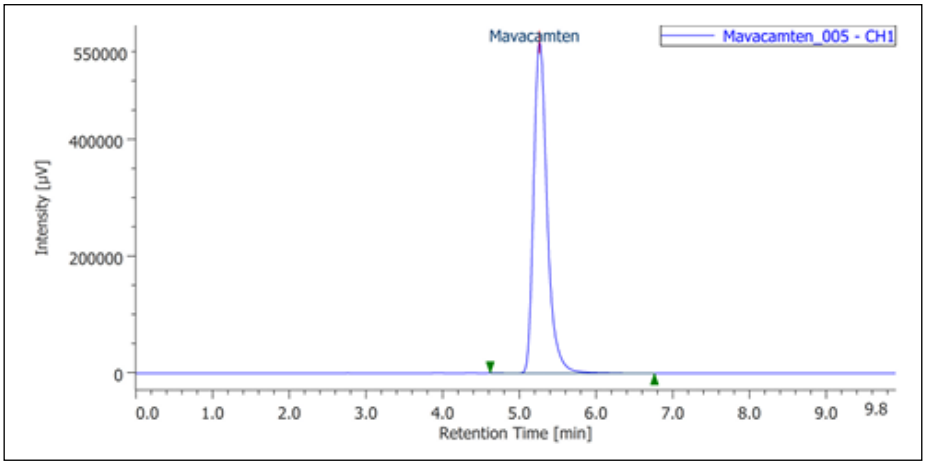

Figure 20- Intermediate Precision (Intraday Afternoon) 1

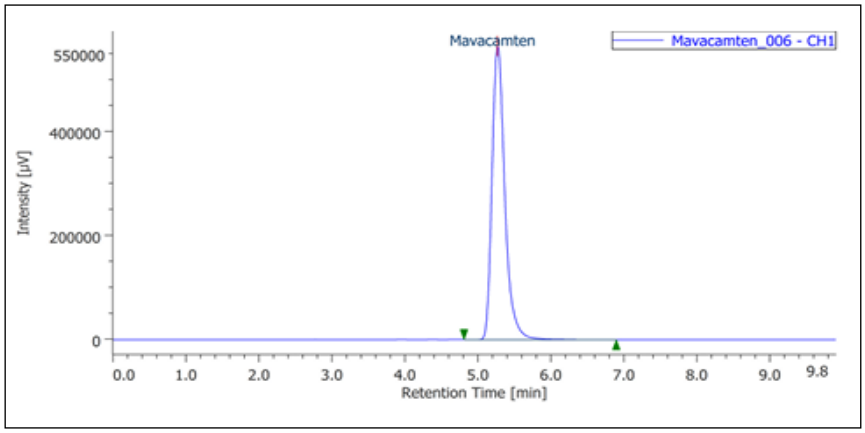

Figure 21- Intermediate Precision (Intraday Afternoon) 2

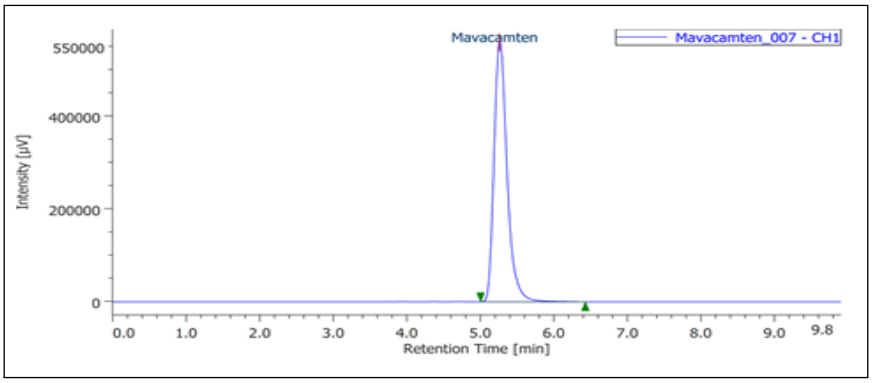

Figure 22- Intermediate Precision (Intraday Afternoon) 3

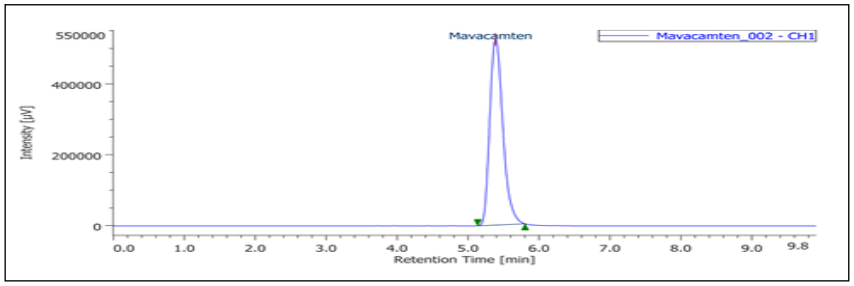

Figure 23- Intermediate Precision (Intraday Evening) 1

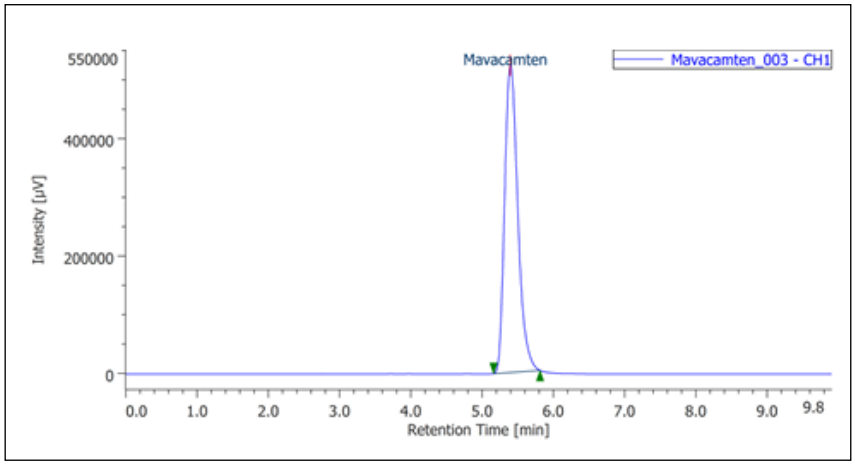

Figure 24- Intermediate Precision (Intraday Evening) 2

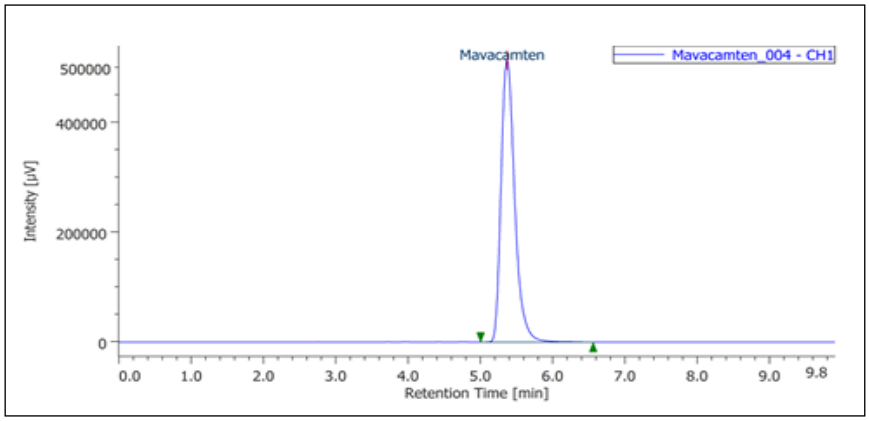

Figure 25- Intermediate Precision (Intraday Evening) 3

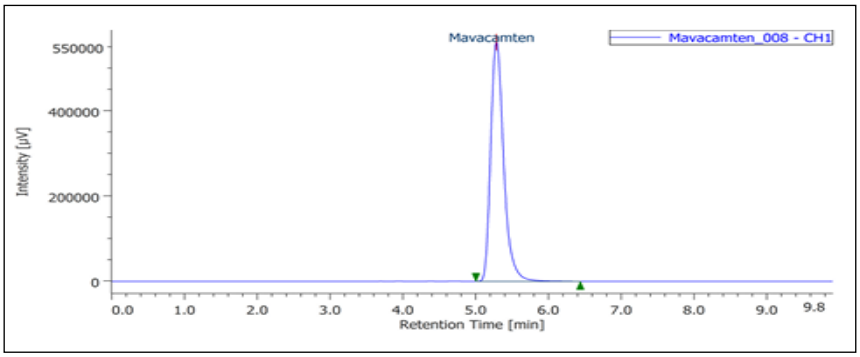

Figure 26- Intermediate Precision (Interday Today) 1

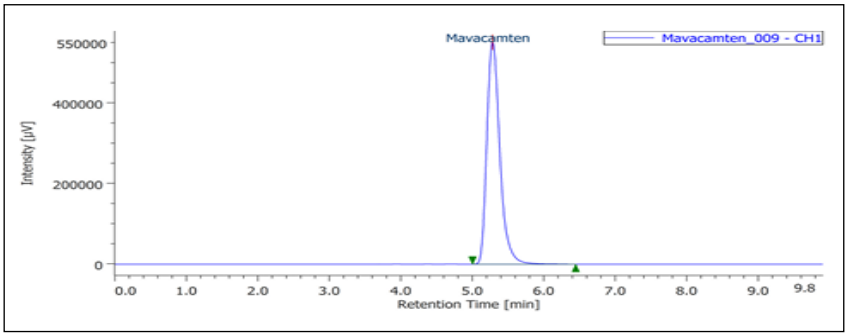

Figure 27- Intermediate Precision (Interday Today) 2

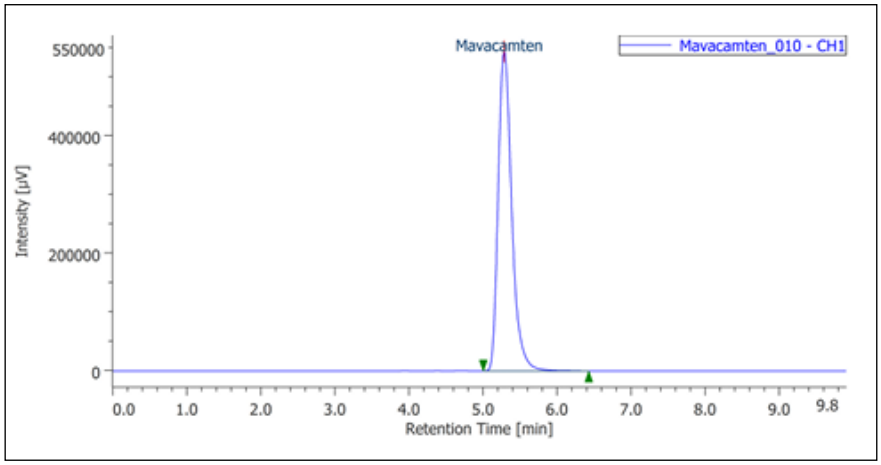

Figure 28- Intermediate Precision (Interday Today) 3

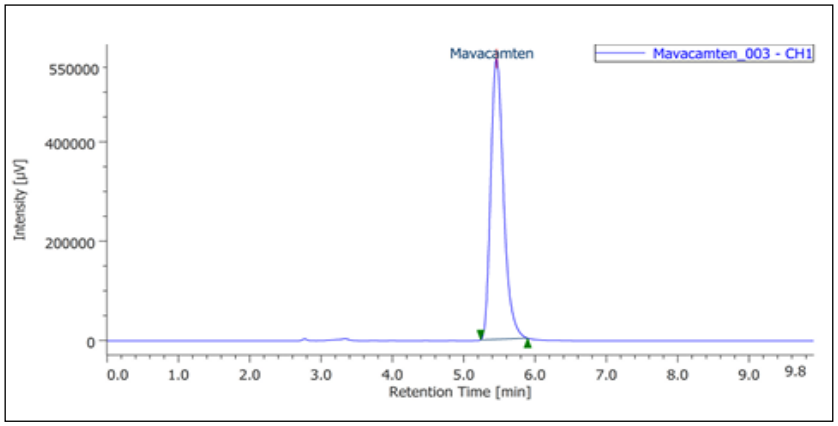

Figure 29- Intermediate Precision (Interday Tomorrow) 1

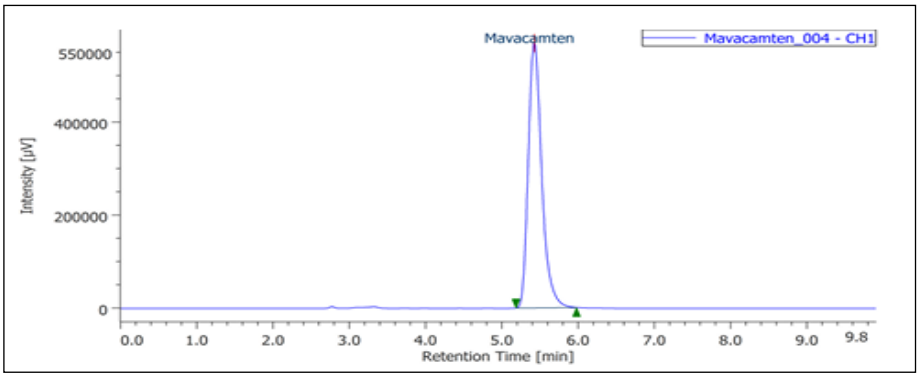

Figure 30- Intermediate Precision (Interday Tomorrow) 2

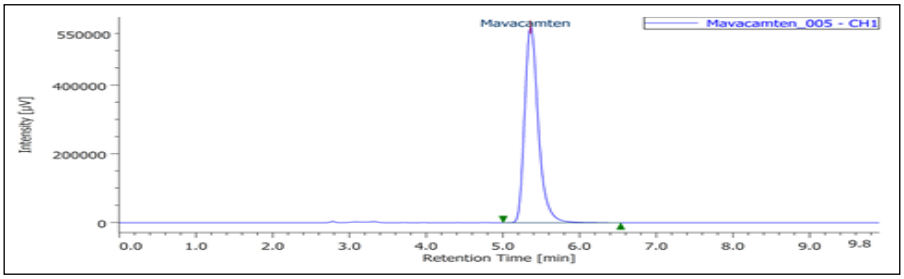

Figure 31- Intermediate Precision (Interday Tomorrow) 3

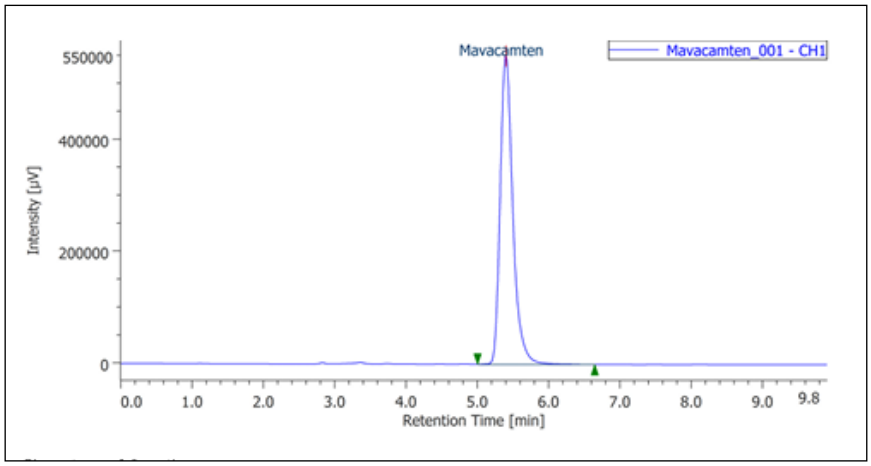

Figure 32- Intermediate Precision (Interday Day after tomorrow) 1

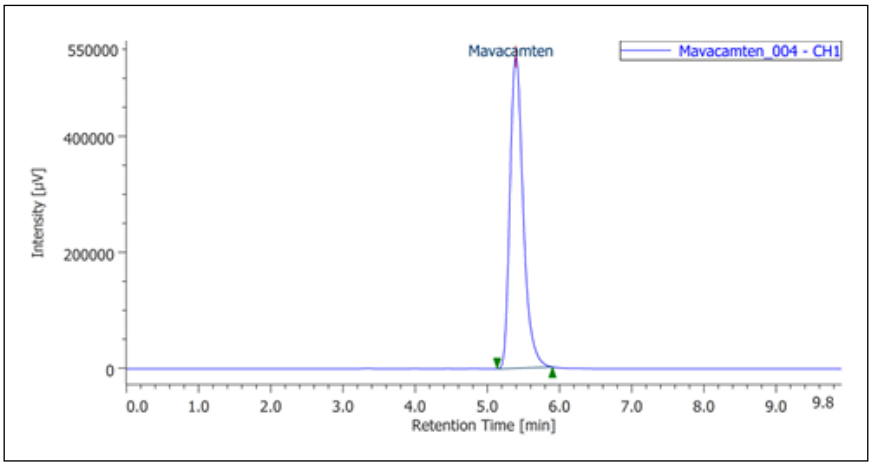

Figure 33- Intermediate Precision (Interday Day after tomorrow) 2

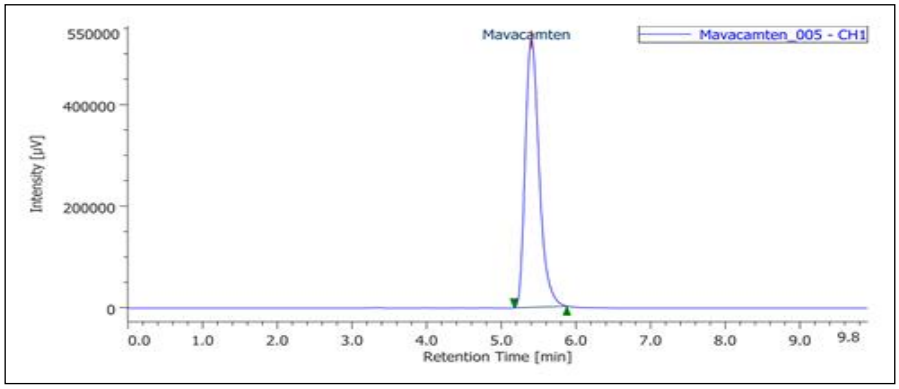

Figure 34- Intermediate Precision (Interday Day after tomorrow) 3

Table 3- Intermediate Precision (Intraday)

Analyte Name	Morning	Afternoon	Evening
Mavacamten	7001565	6963327	6759743
	7021326	6895634	6727662
	7059288	6942180	6765891
Mean	7027393	6933713	6751098
% RSD	0.417%	0.499%	0.304%

Table 4- Intermediate Precision (Interday)

Analyte Name	Today	Tomorrow	Day after tomorrow
Mavacamten	6992210	7091542	6813510
	7003696	7009994	6861616
	6953092	7097561	6847118

Mean	6982999	7066365	6840748
% RSD	0.380%	0.692%	0.361%

Acceptance Criteria:

The relative standard deviation from analysis 1 and analysis 2 should be within the following limits. The overall % RSD for Assay of Mavacamten from interday and intraday should be < 2.0%,

Results and evaluation:

% RSD of % assay results from 3-3 determinations are within acceptance criteria for analysis of intraday and interday.

3.5 Linearity

The linearity of peak area response for sample was determined from 2 to 12 ppm of working concentration of sample. The stock solutions of sample were diluted to six different known concentrations. Graph was plotted of concentration (as x-value) versus area (as y-value). The correlation coefficient (r^2), y-intercept and slope of the regression were calculated and Tabulated in Table 7.

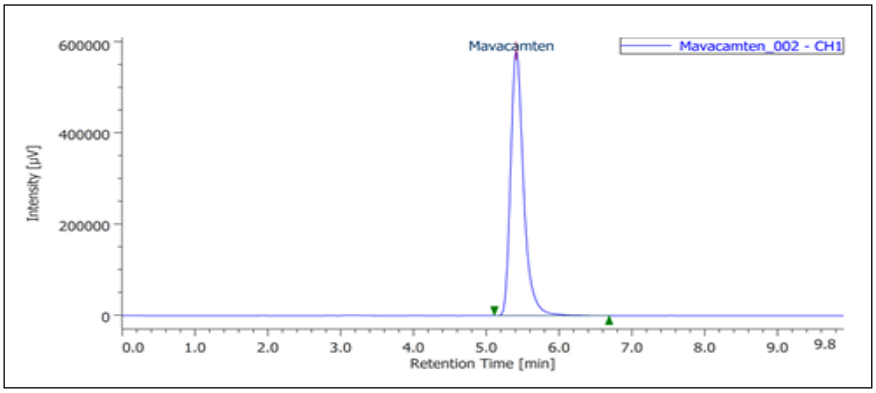

Figure 35- 2 ppm

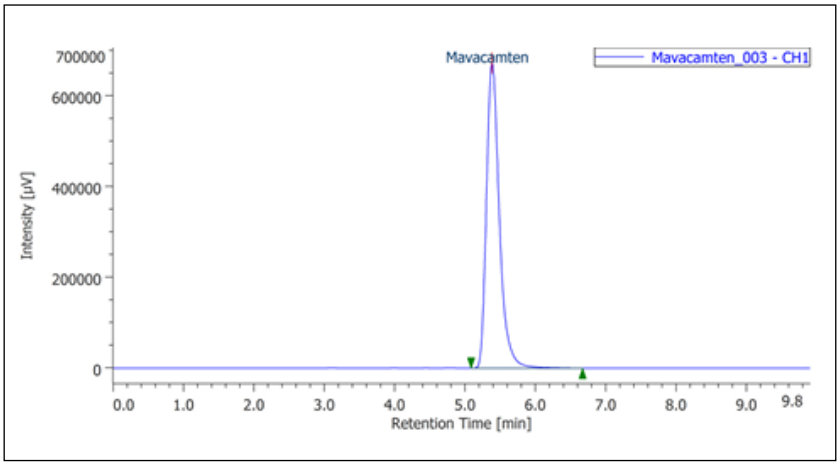

Figure 36- 4 ppm

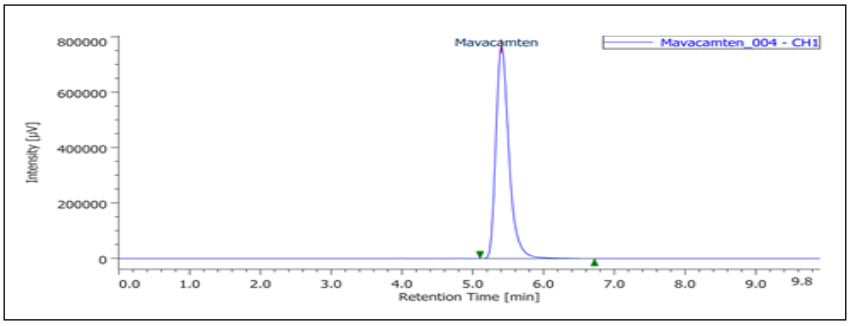

Figure 37- 6 ppm

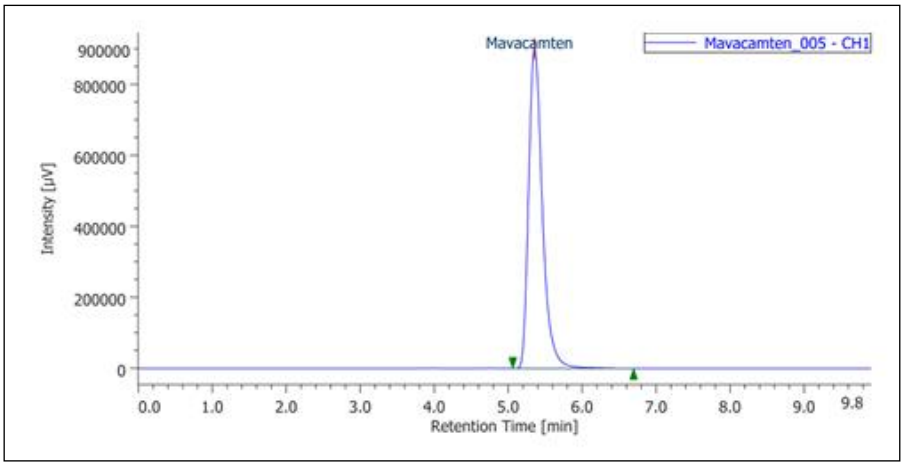

Figure 38- 8 ppm

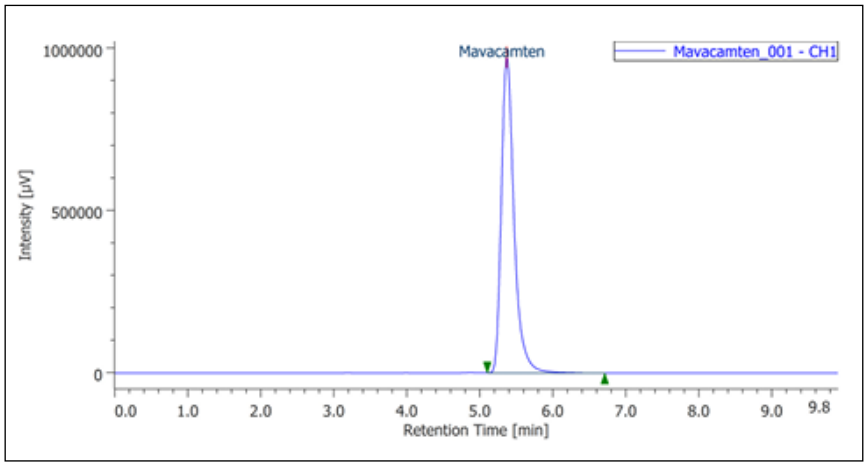

Figure 39- 10 ppm

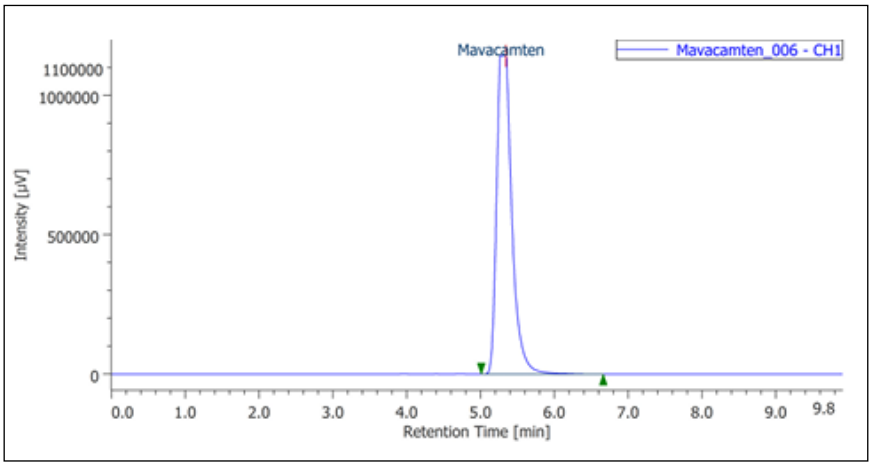

Figure 40- 12 ppm

Table 5- Linearity of Mavacamten

Conc. of Sample (ppm)	Average Peak area
2	3241383
4	5863891
6	8651624
8	11084081
10	13683552

12	16471199
0.997	

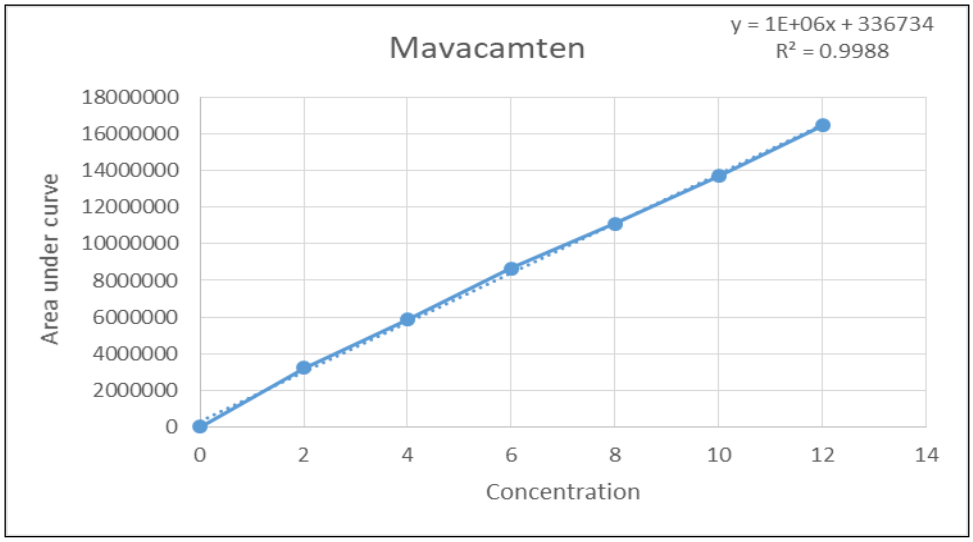

Figure 37- Linear regression curve of Mavacamten

Acceptance Criteria:

The Correlation coefficient (r^2) > 0.9988

Results and evaluation:

Method is considered to be linear as the Correlation coefficient is within acceptance criteria.

3.6 Robustness

The influences of slightly changed parameters of the chromatographic conditions were tested according to ICH guidelines to demonstrate robustness of the method. The tests are carried out by injecting Blank and standard solution by varying same of the parameters of chromatography mentioned below.

Table 14: Robustness parameter

Sr. No	Parameters	Working parameter	- changes	+ changes
1	Flow rate	1 ml/min	0.8 ml/min	1.2 ml/min
2	Injection volume	20 µL	18 µL	22 µL

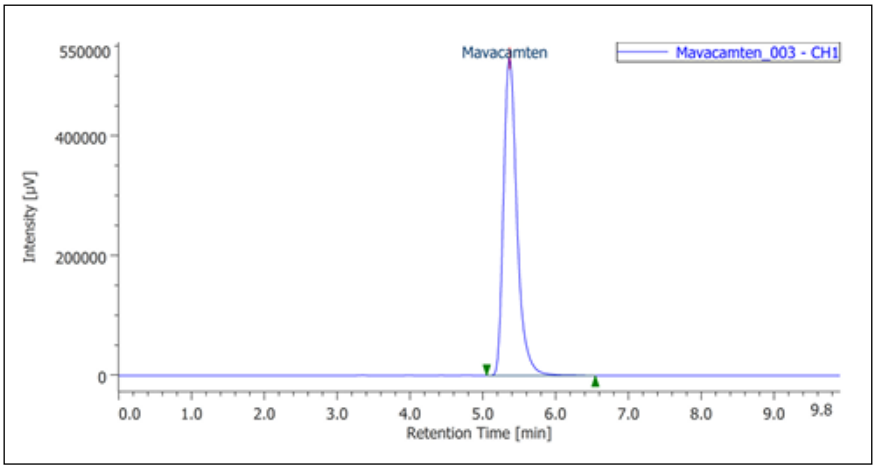

Figure 41- Robustness (Flow rate 0.8 ml/min) 1

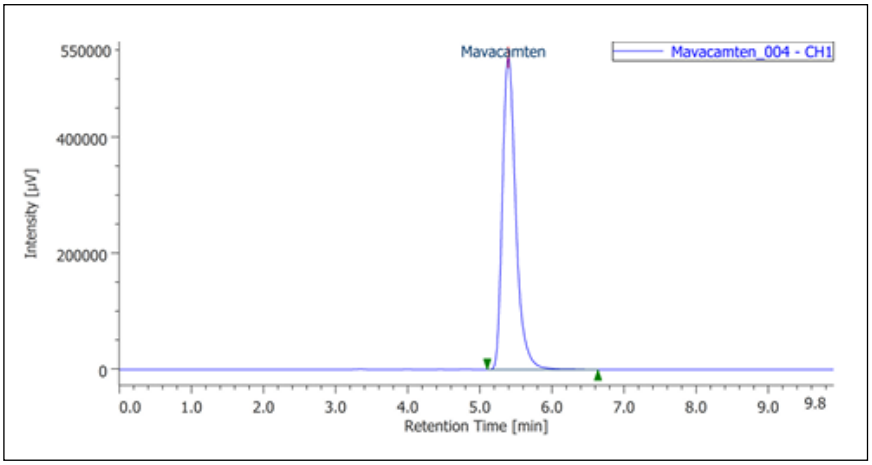

Figure 42- Robustness (Flow rate 0.8 ml/min) 2

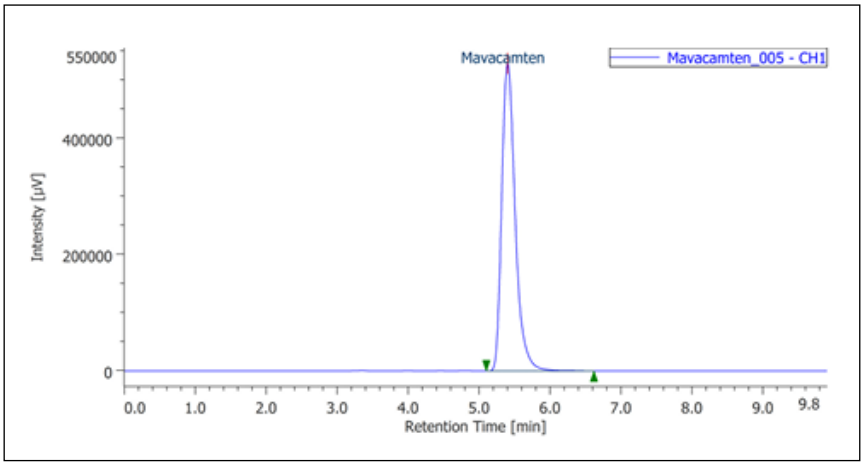

Figure 43- Robustness (Flow rate 0.8 ml/min) 3

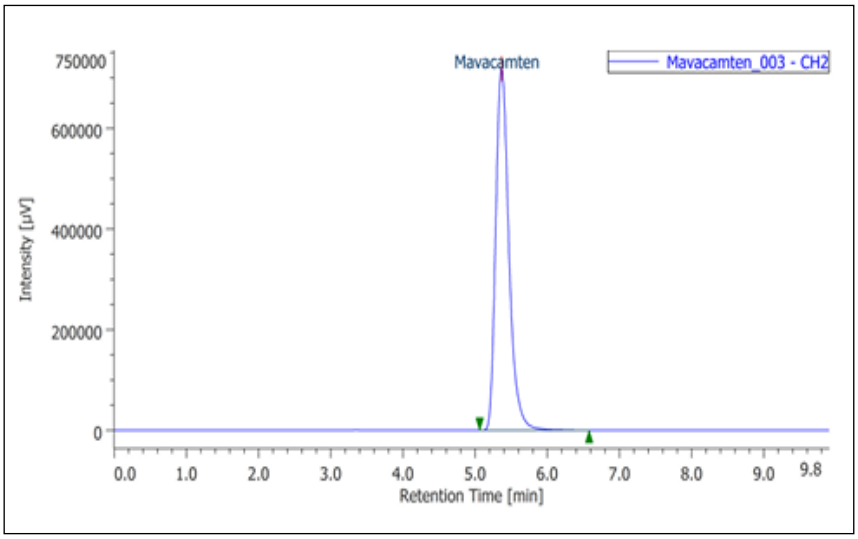

Figure 44- Robustness (Flow rate 1.2 ml/min) 1

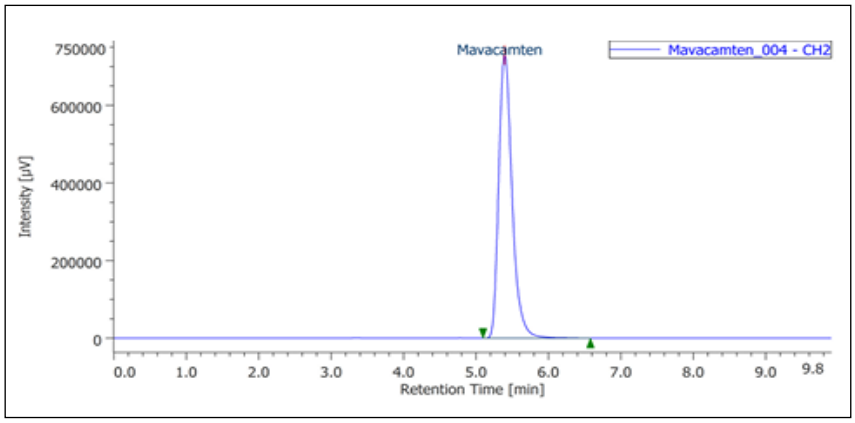

Figure 45- Robustness (Flow rate 1.2 ml/min) 2

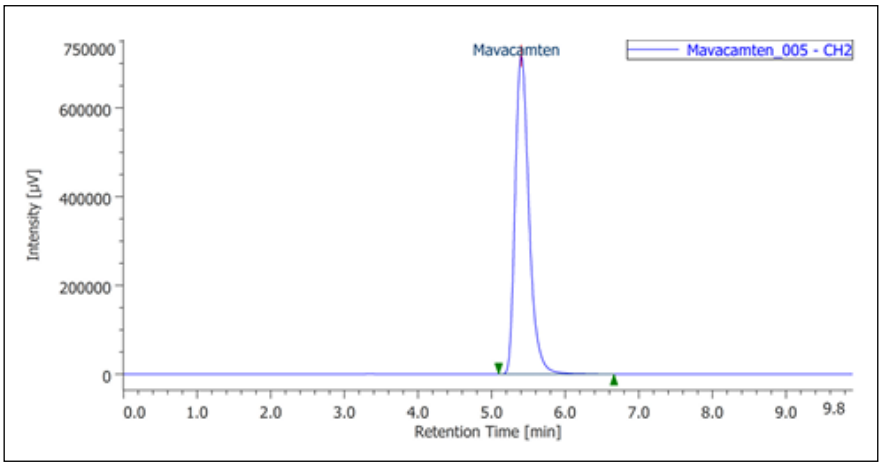

Figure 46- Robustness (Flow rate 1.2 ml/min) 3

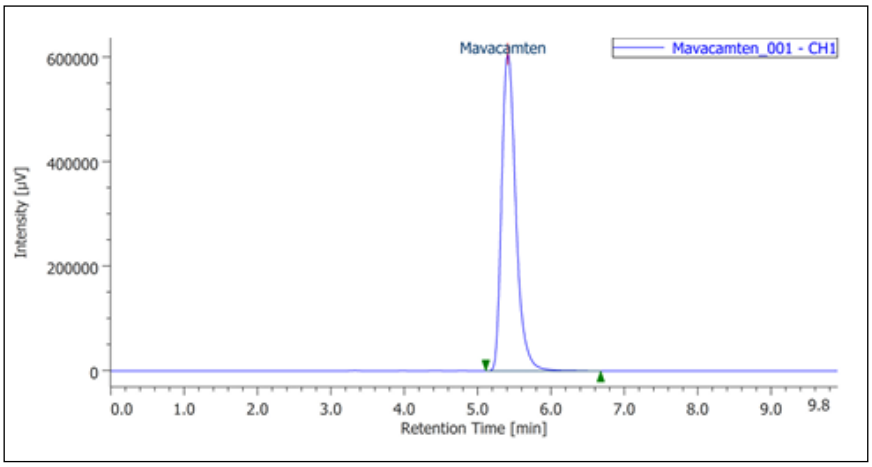

Figure 47- Robustness (Injection volume 18 µL) 1

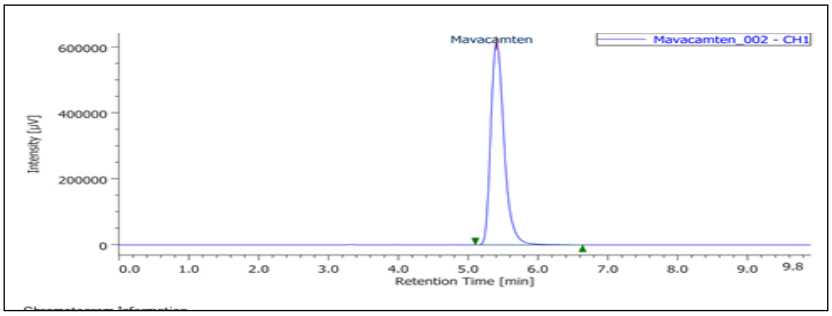

Figure 48- Robustness (Injection volume 18 µL) 2

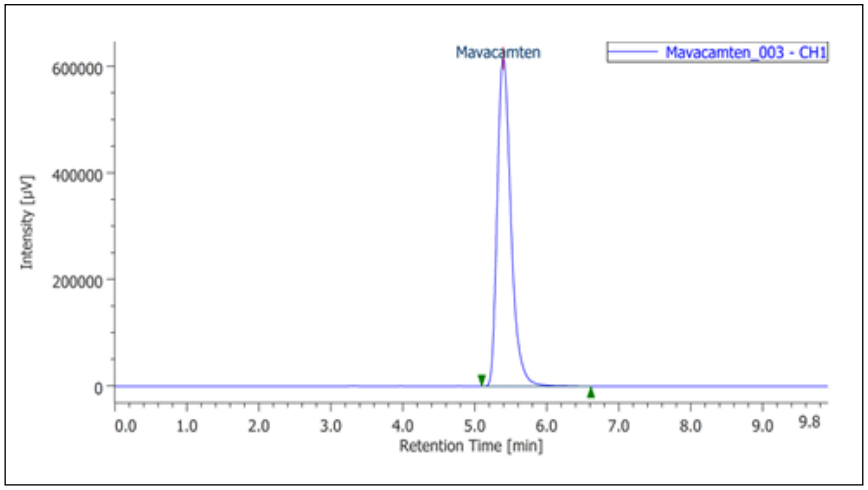

Figure 49- Robustness (Injection volume 18 µL) 3

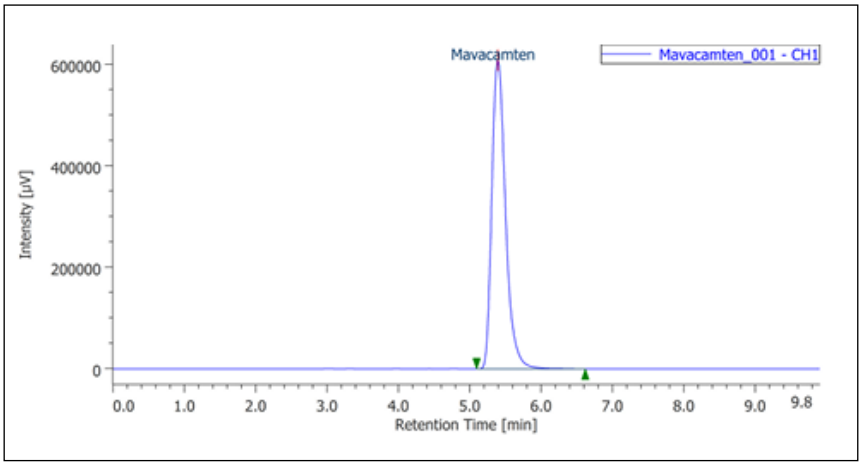

Figure 50- Robustness (Injection volume 22 µL) 1

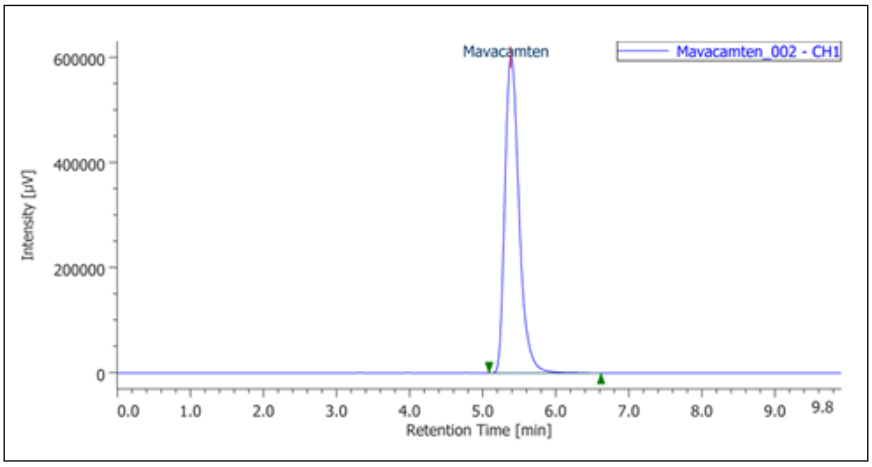

Figure 51- Robustness (Injection volume 22 µL) 2

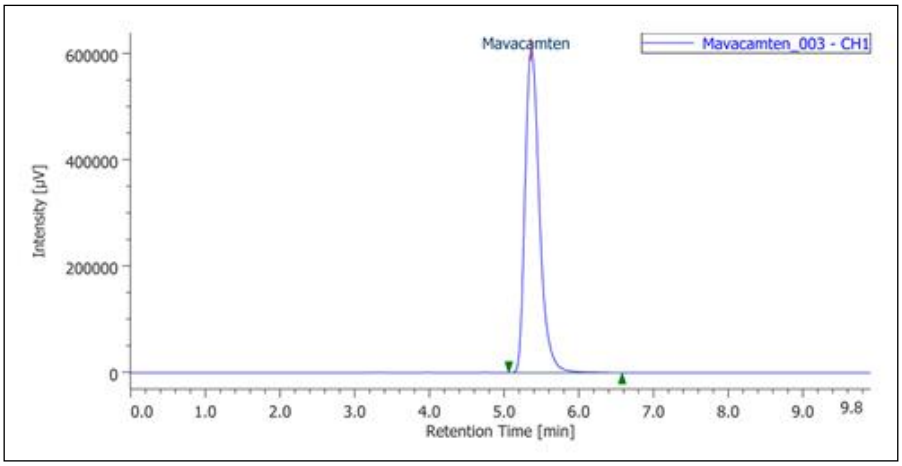

Figure 52- Robustness (Injection volume 22 µL) 3

Table 6- Robustness of Mavacamten

Robustness parameters		**% RSD**	**Peak tailing**	**Theoretical plates**	**Remark**
Sample					
Flow rate (-2 ml/min) and (+2 ml/min)	6822962	1.363%	1.341	4281	Pass
	6974262		1.365	4329	Pass
	6996705		1.369	4124	Pass
	9180342	1.362%	1.303	4393	Pass
	9380498		1.336	4278	Pass
	9415953		1.342	4107	Pass
Injection volume (-2 µl) and (+2 µl)	8175279	0.125%	1.366	3945	Pass
	8168494		1.3690	3978	Pass
	8155245		1.366	4043	Pass
	8152845	0.017%	1.348	3962	Pass
	8152728		1.382	3790	Pass
	8150342		1.381	3907	Pass

Acceptance Criteria:

The % RSD of peak area response due to in 3 replicate injections of sample solution should be less than 2.0 % and system suitability parameters should be passed.

Results and evaluation:

The % RSD and system suitability parameters for results obtained with varied chromatographic conditions are within the limits. Hence, the method is found to be robust.

3.6 LOD and LOQ-

Table 7- LOD and LOQ of Mavacamten

Parameter	**Calculated Value**	**Acceptance Criteria**	**Remark**
LOD	**0.24 ppm**	Signal-to-noise ratio ≈ 3:1	Method is sensitive and capable of detecting low levels of Mavacamten
LOQ	**0.72 ppm**	Signal-to-noise ratio ≈ 10:1	Method is suitable for accurate and precise quantification

Acceptance Criteria-

As per ICH Q2 guidelines, the limit of detection (LOD) corresponds to a signal-to-noise ratio of approximately 3:1, while the limit of quantification (LOQ) corresponds to a signal-to-noise ratio of approximately 10:1.

Result-

The determined LOD and LOQ values comply with the acceptance criteria outlined in ICH Q2(R1), demonstrating that the developed analytical method for Mavacamten possesses adequate sensitivity to detect and accurately quantify the drug at low concentration levels.

4. CONCLUSION -

- The Specificity of the HPLC test for Assay of was proved by chromatographic comparison and method was found to be specific.
- The linearity of the proposed method was determined from the correlation coefficient and the method was found to be linear and within the range of 50 to 150% of working concentration
- The precision of the method was calculated by concentration study & the proposed method was found to be accurate as all the parameter of the method complies as per the acceptance criteria.

5. REFERENCES -

1. Mir KB, Abrol V, Wani TU, Jan I, Singh N, Khan NA, Dar AA, Sultan RMS, Lone SA, Iesa MAM, Alhag SK, Al-Shuraym LA, Helm N, Al-Farga A. Validation and development of RP-HPLC method for quantification of glibenclamide in rat plasma and its application to pharmacokinetic studies in wistar rats. Heliyon. 2023;9(11):e20876
2. Varma MM, Thulluru A, Kumar S, Kumar GS, Pavani K. HPLC method development and validation: A review. World Journal of Pharmaceutical Research. 2021 Jan 1;10:405-26.
3. Gupta S, Verma P, Mishra AP, Omar N, Mathur R. A review on novel analytical method development and validation by RP-HPLC method. Indian Journal of Forensic Medicine & Toxicology. 2021 Sep 5;15(4):3479-86.
4. Olivotto I, Oreziak A, Barriales-Villa R, Abraham TP, Masri A, Garcia-Pavia P, Saberi S, Lakdawala NK, Wheeler MT, Owens A, Kubanek M, Wojakowski W, Jensen MK, Gimeno-Blanes J, Afshar K, Myers J, Hegde SM, Solomon SD, Sehnert AJ, Zhang D, Li W, Bhattacharya M, Edelberg JM, Waldman CB, Lester SJ, Wang A, Ho CY, Jacoby D., EXPLORER-HCM study investigators. Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2020 Sep 12;396(10253):759-769.
5. Xie J, Wang Y, Xu Y, Fine JT, Lam J, Garrison LP. Assessing health-related quality-of-life in patients with symptomatic obstructive hypertrophic cardiomyopathy: EQ-5D-based utilities in the EXPLORER-HCM trial. J Med Econ. 2022 Jan-Dec;25(1):51-58.
6. Saberi S, Cardim N, Yamani M, Schulz-Menger J, Li W, Florea V, Sehnert AJ, Kwong RY, Jerosch-Herold M, Masri A, Owens A, Lakdawala NK, Kramer CM, Sherrid M, Seidler T, Wang A, Sedaghat-Hamedani F, Meder B, Havakuk O, Jacoby D. Mavacamten Favorably Impacts Cardiac Structure in Obstructive Hypertrophic Cardiomyopathy: EXPLORER-HCM Cardiac Magnetic Resonance Substudy Analysis. Circulation. 2021 Feb 09;143(6):606-608.
7. Desai N, Xie J, Wang Y, Sutton MB, Whang J, Fine JT, Garrison LP. Projecting the Long-term Clinical Value of Mavacamten for the Treatment of Obstructive Hypertrophic Cardiomyopathy in the United States: An Assessment of

Net Health Benefit. Clin Ther. 2022 Jan;44(1):52-66.e2.

8. Ho CY, Mealiffe ME, Bach RG, Bhattacharya M, Choudhury L, Edelberg JM, Hegde SM, Jacoby D, Lakdawala NK, Lester SJ, Ma Y, Marian AJ, Nagueh SF, Owens A, Rader F, Saberi S, Sehnert AJ, Sherrid MV, Solomon SD, Wang A, Wever-Pinzon O, Wong TC, Heitner SB. Evaluation of Mavacamten in Symptomatic Patients With Nonobstructive Hypertrophic Cardiomyopathy. J Am Coll Cardiol. 2020 Jun 02;75(21):2649-2660.
9. Edelberg JM, Sehnert AJ, Mealiffe ME, et al. The impact of mavacamten on the pathophysiology of hypertrophic cardiomyopathy: a narrative review. Am J Cardiovasc Drugs. 2022. https://doi.org/10.1007/s40256-022-00532-x.
10. Golla VM, Pilli P, Padhy HP, Samanthula G, Gupta AK. Analytical challenges in the mavacamten impurity analysis: Exploring various cutting edge analytical methods to achieve mass balance for the accurate quantification of analytes. Journal of the Indian Chemical Society. 2025 Sep 3:102082.
11. Bello J, Pellegrini MV. Mavacamten. InStatPearls [Internet] 2024 Aug 21. StatPearls Publishing.
12. Keam SJ. Mavacamten: First Approval: SJ Keam. Drugs. 2022 Jul;82(10):1127-35.
13. Braunwald E, Saberi S, Abraham TP, Elliott PM, Olivotto I. Mavacamten: a first-in-class myosin inhibitor for obstructive hypertrophic cardiomyopathy. European Heart Journal. 2023 Nov 21;44(44):4622-33.
14. Desai MY, Owens AT, Abraham T, Olivotto I, Garcia-Pavia P, Lopes RD, Elliott P, Fernandes F, Verheyen N, Maier L, Meder B. Mavacamten in symptomatic nonobstructive hypertrophic cardiomyopathy. New England Journal of Medicine. 2025 Sep 11;393(10):961-72.
15. Schenk A, Fields N. Mavacamten—a targeted therapy for hypertrophic cardiomyopathy. Journal of Cardiovascular Pharmacology. 2023 May 1;81(5):317-26.
16. Golla, V.M., Kalyan, M., Gholap, U., Padhy, H.P., Ramachandran, R.K. and Samanthula, G., 2024. Discerning the stability behaviour of mavacamten availing liquid chromatography-mass spectrometry and nuclear magnetic resonance spectroscopy: In silico toxicity and mutagenicity prediction of degradation products. *Journal of Mass Spectrometry*, *59*(3), p.e5007.
17. Ganjiwale SV, Dewani AP, Chandewar AV. A comprehensive overview of HPLC method development and validation. Int J Pharm Sci. 2024;2:1.
18. Phadtare M, Aher S, Phadtare DG, Bacchav RS, Patil A. A Review On Development And Validation Of Hplc Method For Analysis Of Pharmaceutical Drug. Journal of Neonatal Surgery. 2025;14(26s).
19. Vidushi Y, Meenakshi B, Bharkatiya M. A review on HPLC method development and validation. Res J Life Sci, Bioinform, Pharm Chem Sci. 2017;2(6):178.
20. Patil MP. HPLC Method Development–A Review. Journal of Pharmaceutical Research and Education. 2017;1(2):243-60.