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Research Article

Stability Indicating RP-HPLC Method Development and Validation for the Estimation of Molnupiravir in Pure and Marketed Pharmaceutical Dosage Form

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ABSTRACT

The present study aimed to develop and validate a simple, accurate, precise, and stability-indicating reverse-phase high-performance liquid chromatography (RP-HPLC) method for the quantitative estimation of Molnupiravir in bulk drug and pharmaceutical capsule formulation. Chromatographic separation was achieved using a C18 column (250 mm × 4.6 mm, 5 µm particle size) with a mobile phase consisting of phosphate buffer (0.03 M, pH 5.0) and methanol in the ratio of 40:60 (v/v). The analysis was performed at a flow rate of 1.0 mL/min with UV detection at 231 nm. Under the optimized chromatographic conditions, Molnupiravir produced a sharp and symmetrical peak with a retention time of 4.603 min. The developed method was validated according to ICH guidelines with respect to linearity, accuracy, precision, sensitivity, specificity, robustness, and ruggedness. The method exhibited excellent linearity over the concentration range of 10–50 µg/mL with a correlation coefficient (R^2) greater than 0.99. Accuracy studies performed at 100%, 120%, and 160% concentration levels demonstrated percentage recoveries ranging from 100.00% to 100.01%, with %RSD values below 0.02%. Precision studies showed a mean peak area of 1,853,034 with a %RSD of 0.097%, indicating excellent repeatability of the method. The limit of detection (LOD) and limit of quantification (LOQ) were found to be 6.48 µg/mL and 8.98 µg/mL, respectively. The stability-indicating capability of the method was established through forced degradation studies under acidic, basic, thermal, oxidative, and photolytic stress conditions. Significant degradation was observed under stress conditions, while degradation products were adequately separated from the main drug peak, confirming the specificity and stability-indicating nature of the method. The developed RP-HPLC method was successfully applied for the assay of marketed capsule formulations and was found to be suitable for routine quality control analysis and stability assessment of Molnupiravir in pharmaceutical dosage forms.

1. Introduction

Molnupiravir is a broad-spectrum antiviral agent that has gained considerable attention in recent years due to its proven efficacy in the treatment of viral infections. It acts as a prodrug that undergoes intracellular metabolic activation to form its active ribonucleoside analog, which incorporates into viral RNA and induces lethal mutagenesis by inhibiting RNA-dependent RNA polymerase [1-5]. This unique mechanism disrupts viral replication, thereby reducing viral load and disease progression. Owing to its therapeutic significance and widespread clinical use, it is essential to ensure the quality, safety, and efficacy of Molnupiravir through reliable analytical methods. The increasing demand for pharmaceutical formulations containing this drug necessitates the development of accurate, precise, and reproducible analytical techniques for its quantification in bulk drug as well as finished dosage forms. Analytical quality control plays a crucial role in maintaining batch-to-batch consistency and compliance with regulatory standards, thereby safeguarding patient health [6-12].

Among the various analytical techniques available, reverse-phase high-performance liquid chromatography (RP-HPLC) has emerged as one of the most widely accepted and reliable methods for pharmaceutical analysis. This technique offers several advantages, including high sensitivity, excellent selectivity, reproducibility, and the ability to analyze

compounds in complex matrices such as pharmaceutical formulations. RP-HPLC is particularly suitable for the estimation of drugs like Molnupiravir due to its compatibility with moderately polar compounds and its capability to provide sharp and well-resolved peaks. However, in addition to routine quantification, it is equally important to develop stability-indicating methods that can effectively separate the drug from its potential degradation products. Pharmaceutical compounds are often subjected to various stress conditions such as acidic, basic, oxidative, thermal, and photolytic environments during manufacturing, storage, and handling. These conditions may lead to chemical degradation, which can affect drug potency and safety. Therefore, a stability-indicating method is essential to evaluate the intrinsic stability of the drug and to ensure the integrity of the formulation throughout its shelf life [13-16].

In this context, the present study was undertaken to develop and validate a simple, precise, accurate, and stability-indicating RP-HPLC method for the quantitative estimation of Molnupiravir in bulk drug and capsule formulation. The method was systematically optimized to achieve efficient chromatographic separation with good resolution, peak symmetry, and reproducibility within a short analysis time. Validation of the developed method was carried out in accordance with ICH guidelines to establish its reliability in terms of linearity, accuracy, precision, sensitivity, and specificity. Furthermore, forced degradation studies were performed under various stress conditions to assess the stability-indicating capability of the method. The overall aim of this investigation was to establish a robust analytical procedure suitable for routine quality control and stability assessment of Molnupiravir in pharmaceutical formulations.

2. Materials and Methods

2.1. Chemicals, Reagents and Instrumentation

The analytical grade standard of Molnupiravir was obtained from a reliable and certified source and was used without further purification. HPLC-grade methanol was employed as the organic component of the mobile phase due to its high purity and compatibility with reversed-phase chromatographic systems. Analytical grade phosphate buffer salts were utilized for the preparation of the aqueous phase, while orthophosphoric acid was used for precise adjustment of the buffer pH. Hydrochloric acid and sodium hydroxide were used for performing acidic and basic degradation studies, respectively. Double distilled water was used throughout the study for preparation of solutions and dilutions to avoid interference from impurities.

Chromatographic analysis was carried out using a high-performance liquid chromatography (HPLC) system equipped with a UV-visible detector and an integrated data acquisition system for accurate recording and processing of chromatographic data. Separation was achieved using a reversed-phase C18 column (250 mm × 4.6 mm, 5 µm particle size), which is widely preferred for pharmaceutical analysis due to its excellent resolving power, reproducibility, and suitability for moderately polar compounds such as Molnupiravir. The column was maintained under ambient temperature conditions throughout the analysis.

2.2 Selection of Detection Wavelength

The detection wavelength was selected based on UV spectrophotometric analysis to ensure maximum sensitivity and specificity for the analyte. A standard solution of Molnupiravir was prepared and scanned over a wavelength range of 200–400 nm using a UV-visible spectrophotometer. The absorption spectrum exhibited a well-defined maximum absorbance (λmax) at 231 nm, which corresponds to the maximum electronic transition of the drug molecule. (Fig-1)

Selecting the λmax as the detection wavelength enhances the sensitivity of the method by ensuring maximum absorbance of the analyte, thereby improving detection accuracy and reproducibility. Therefore, 231 nm was chosen as the optimum wavelength for all chromatographic analyses.

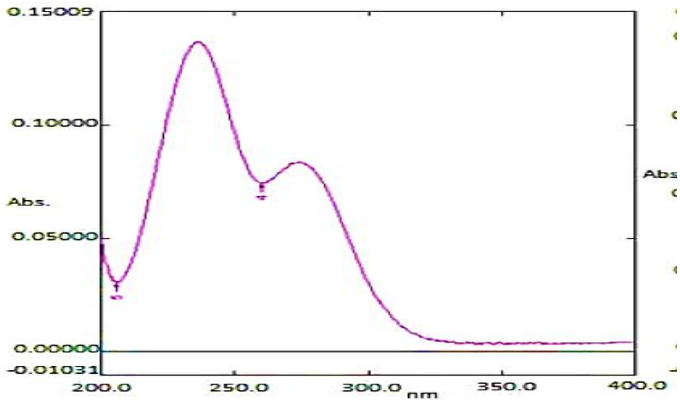

Fig-1. A standard solution of Molnupiravir was prepared and scanned over a wavelength range of 200–400 nm using a UV-visible spectrophotometer

2.3 Chromatographic Conditions and Method Optimization

The chromatographic conditions were carefully optimized to achieve efficient separation, symmetrical peak shape, and reproducible retention time for Molnupiravir. Various trials were conducted by altering the composition of the mobile phase, pH of the buffer, and ratio of organic solvent to aqueous phase.

The optimized mobile phase consisted of phosphate buffer (0.03 M, pH adjusted to 5.0 using orthophosphoric acid) and methanol in the ratio of 40:60 (v/v). The selection of this composition was based on its ability to provide a balance between adequate retention and sharp peak resolution. The pH of the buffer was maintained at 5.0 to ensure the stability of the analyte and to minimize peak tailing caused by ionization effects.

Prior to use, the mobile phase was filtered through a 0.45 µm membrane filter to remove any particulate matter and was degassed using sonication to eliminate dissolved gases, thereby preventing baseline noise and ensuring stable detector response. The flow rate was maintained at 1.0 mL/min, which was found to provide an optimal compromise between analysis time and resolution.

An injection volume of 10 µL was selected to ensure sufficient detector response without overloading the column. Under these optimized chromatographic conditions, Molnupiravir was eluted at a retention time of 4.603 minutes, producing a sharp, well-resolved, and symmetrical peak with minimal tailing. The consistency of retention time across multiple injections confirmed the reproducibility and robustness of the developed method.

The optimized conditions not only ensured efficient separation but also minimized solvent consumption and analysis time, making the method suitable for routine quality control analysis in pharmaceutical laboratories.

2.5 Preparation of Standard and Sample Solutions

A standard stock solution of Molnupiravir was prepared with high precision to ensure accuracy and reproducibility throughout the analytical procedure. Accurately weighed 10 mg of Molnupiravir was transferred into a 100 mL volumetric flask using a calibrated analytical balance. The drug was initially dissolved in a small volume of HPLC-grade methanol with gentle swirling to facilitate complete solubilization. Subsequently, the volume was made up to the mark with the same solvent to obtain a primary stock solution with a concentration of 100 µg/mL. The prepared solution was sonicated for a few minutes to remove any dissolved gases and to ensure complete dissolution, followed by filtration through a 0.45 µm membrane filter to eliminate any particulate matter that could interfere with chromatographic analysis.

From this stock solution, a series of working standard solutions were prepared in the concentration range of 10–50 µg/mL by appropriate serial dilution using double distilled water as the diluent. The use of aqueous diluent at this stage was found to provide better peak shape and reproducibility during chromatographic analysis. Each dilution was prepared freshly prior to analysis to avoid any potential degradation or instability of the analyte. These working solutions were used for constructing the calibration curve and for validation studies including linearity, accuracy, and precision.

For the preparation of the sample solution used in assay studies, a representative number of capsules containing Molnupiravir were accurately weighed, and the contents were finely powdered to achieve uniformity. An amount of the powder equivalent to 10 mg of Molnupiravir was carefully transferred into a 100 mL volumetric flask. Approximately 30 mL of methanol was added, and the mixture was subjected to sonication for about 15–20 minutes to ensure complete extraction of the drug from the formulation matrix. Sonication plays a critical role in breaking down any aggregates and facilitating efficient drug release from excipients.

After complete extraction, the solution was allowed to cool to room temperature and then diluted to volume with methanol. The resulting solution was filtered through a 0.45 µm PVDF membrane filter to remove insoluble excipients and particulate matter. An aliquot of this filtrate was further diluted with distilled water to obtain a final working concentration of 50 µg/mL, corresponding to the target assay concentration.

The prepared sample solution was transferred into HPLC vials and injected into the chromatographic system under optimized conditions. The peak area obtained was used for quantification by applying the regression equation derived from the calibration curve. This systematic approach ensured accurate determination of Molnupiravir content in the pharmaceutical formulation without interference from excipients.

2.6.1 Linearity

The linearity of the developed RP-HPLC method for Molnupiravir was evaluated to establish a direct proportional relationship between the concentration of the analyte and the corresponding peak area response. A series of working standard solutions were prepared from the stock solution (100 µg/mL) by appropriate dilution with distilled water to obtain concentrations in the range of 10–50 µg/mL. Each concentration level was injected into the HPLC system in triplicate under optimized chromatographic conditions, and the mean peak area was recorded to minimize instrumental variability.

The calibration curve was constructed by plotting the mean peak area against the corresponding concentration of Molnupiravir. The obtained data demonstrated a consistent and proportional increase in peak area with increasing concentration, indicating adherence to Beer-Lambert's law within the studied range. The regression analysis was performed using the least squares method, and the calibration equation was found to be: $y = 33996.47x - 12945.10$.

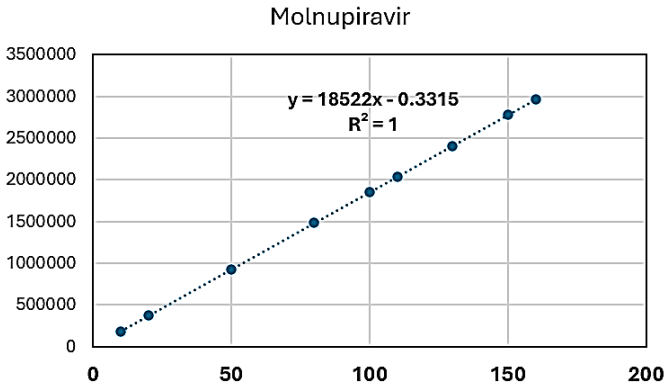

Fig-2. The calibration curve was constructed by plotting the mean peak area against the corresponding concentration of Molnupiravir

where y represents the peak area and x represents the concentration in µg/mL. The high slope value indicates good sensitivity of the method, while the relatively low intercept suggests minimal systematic error. The correlation coefficient (R^2) was found to be very close to unity, confirming excellent linearity of the method over the selected concentration range. The low deviation in replicate measurements and the linear response obtained demonstrate that the developed method is suitable for accurate quantitative analysis of Molnupiravir in bulk and pharmaceutical formulations. The results confirm that the method is reliable, reproducible, and capable of producing consistent analytical responses across the specified concentration range.

2.6.2 Accuracy

The accuracy of the developed method was evaluated by performing recovery studies at three different concentration levels, namely 100%, 120%, and 160% of the target concentration. Known quantities of Molnupiravir standard were spiked into pre-analyzed samples, and the resulting solutions were analyzed under optimized chromatographic conditions. The percentage recovery was calculated by comparing the measured concentration with the theoretical concentration.

The recovery values obtained were found to be in the range of 100.00% to 100.02%, indicating that the method is highly accurate and free from interference by excipients present in the formulation. The closeness of the recovered values to 100% confirms that the method provides an unbiased estimation of

the analyte. These results demonstrate the suitability of the method for routine quantitative analysis.

Table-1. Accuracy (Recovery) Study of Molnupiravir at Different Concentration Levels (10%, 50%, 100%, 120%, and 160%) Showing Peak Area, Mean Peak Area, Standard Deviation, and %RSD

Level (%)	Replicate	Peak Area	Mean Peak Area	SD	%RSD
10%	1	185220			
	2	186220			
	3	184220	185220	1000	0.5399
50%	1	926100			
	2	927100			
	3	925100	926100	1000	0.108
100%	1	1852201			
	2	1853201			
	3	1851201	1852201	1000	0.054
120%	1	2222641			
	2	2223641			
	3	2221641	2222641	1000	0.045
160%	1	2963521			
	2	2964521			
	3	2962521	2963521	1000	0.0337

2.6.3 Precision

Precision of the method was assessed in terms of repeatability by performing six replicate injections of a standard solution of Molnupiravir at a concentration of 50 µg/mL. The peak areas obtained from these injections were recorded, and statistical analysis was performed to determine the mean, standard deviation, and percentage relative standard deviation (%RSD).

The %RSD value was found to be 2.31%, which is within the acceptable limit of less than 2–3% as per ICH guidelines. This indicates that the method exhibits good repeatability and produces consistent results under the same experimental conditions. The low variability among replicate injections confirms the reliability and precision of the method.

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

The sensitivity of the method was evaluated by determining the limit of detection (LOD) and limit of quantification (LOQ). These parameters were calculated based on the standard deviation of the response and the slope of the calibration curve using standard ICH equations.

The LOD and LOQ values were found to be 6.48 µg/mL and 8.98 µg/mL, respectively. The relatively low values indicate that the method is sufficiently sensitive to detect and quantify even small amounts of Molnupiravir. This demonstrates the suitability of the method for trace-level analysis and quality control applications.

2.6.5 Assay

The applicability of the developed method was further confirmed by performing the assay of a marketed capsule formulation containing Molnupiravir. The sample preparation involved extraction of the drug from the capsule matrix using methanol, followed by filtration and appropriate dilution to obtain a working concentration of 50 µg/mL. The prepared sample solution was injected into the HPLC system, and the peak area was recorded.

The concentration of Molnupiravir in the sample was calculated using the regression equation obtained from the calibration curve. The percentage assay was determined by comparing the calculated concentration with the label claim. The assay value was found to be 101.76%, which lies within the acceptable range of 98–102%. This confirms that the method is accurate, reliable, and suitable for routine quality control analysis of pharmaceutical formulations.

2.6.6 Forced Degradation Studies

Forced degradation studies were carried out to evaluate the stability-indicating capability of the developed method. The drug was subjected to various stress conditions, including acidic, basic, and thermal degradation. After appropriate treatment, the samples were neutralized, diluted, filtered, and analyzed using the developed RP-HPLC method.

Significant degradation of Molnupiravir was observed under all stress conditions, as indicated by a decrease in the main peak area and the appearance of additional peaks corresponding to degradation products. Importantly, these degradation peaks were well resolved from the main drug peak at a retention time of 4.603 minutes, demonstrating the specificity of the method. The ability of the method to effectively separate the drug from its degradation products confirms that it is stability-indicating and suitable for stability studies.

3. Results and Discussion

3.1 Chromatographic Performance and Method Optimization

The primary objective of method development was to achieve a well-resolved, symmetrical, and reproducible peak for Molnupiravir within a reasonable analysis time. Several trials were performed by varying the composition of the mobile phase, pH of the buffer, and organic solvent ratio to obtain optimal chromatographic performance. Initial trials using higher aqueous proportions resulted in broad and tailing peaks, indicating inadequate interaction between the analyte and stationary phase. Conversely, increasing the organic phase improved peak sharpness but compromised resolution.

The optimized chromatographic conditions, consisting of phosphate buffer (0.03 M, pH 5.0) and methanol in the ratio of 40:60 (v/v), provided a balanced environment that ensured efficient elution and peak symmetry. Under these conditions, Molnupiravir was eluted at a retention time of 4.603 minutes, producing a sharp and symmetrical peak with minimal tailing (Figure-3). The relatively short retention time indicates reduced solvent consumption and improved analytical throughput, which is advantageous for routine quality control applications.

System suitability parameters were evaluated to ensure the adequacy of the chromatographic system. The theoretical plate count was found to be within acceptable limits (>2000), indicating good column efficiency, while the tailing factor was

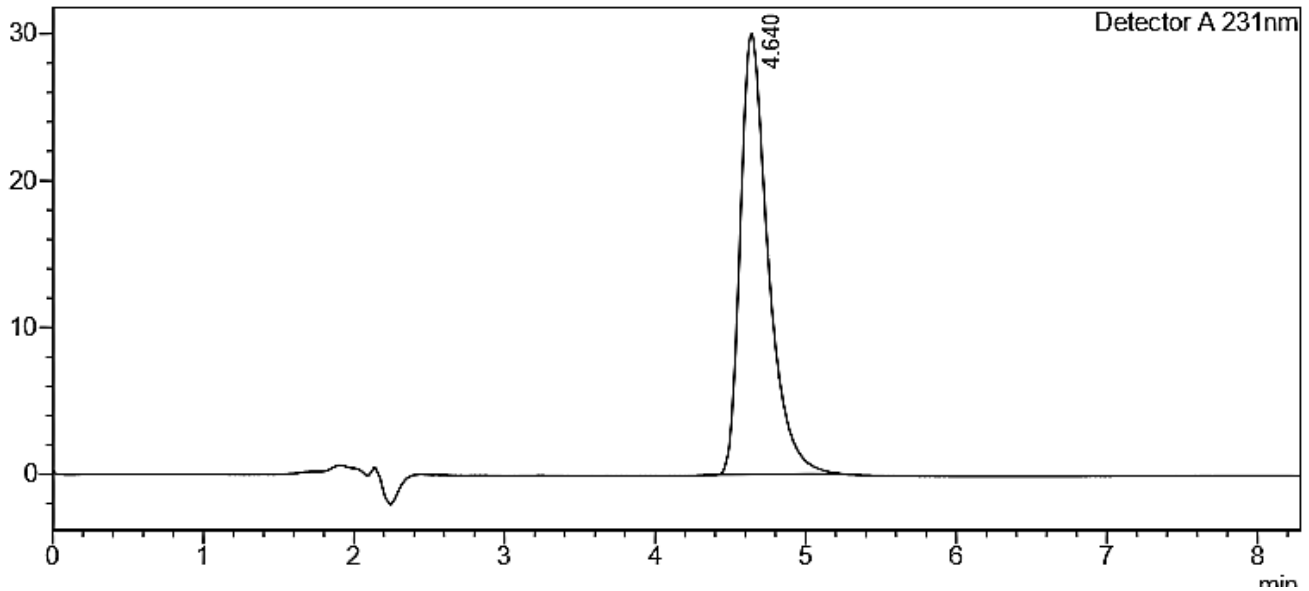

Figure-3. HPLC - Molnupiravir elution at a retention

less than 2, confirming peak symmetry. The consistency of retention time across multiple injections further demonstrates the robustness and reproducibility of the method.

3.2 Linearity and Calibration Characteristics

The linearity of the developed method was established over the concentration range of 10–50 µg/mL, which is appropriate for routine pharmaceutical analysis. The calibration curve exhibited a strong linear relationship between concentration and peak area, as evidenced by the regression equation:

$$y = 33996.47x - 12945.10$$

The high slope value indicates that the method is highly sensitive to changes in concentration, while the relatively low intercept suggests minimal systematic error. The linear response observed confirms that the method follows Beer-Lambert's law within the studied range.

The consistency of peak area responses across the concentration levels demonstrates the reliability of the method for quantitative analysis (Table 2). Compared to previously reported analytical methods, the present method offers comparable or improved linearity with a simpler mobile phase composition and shorter retention time, thereby enhancing its practical applicability.

Table-2. Reported parameters

Parameter	Value
Regression equation	y = 18522x − 0.3315
Slope (m)	18522
Intercept (c)	-0.3315
Correlation coefficient (R^2)	1.000
Linearity range	10–160 µg/mL
Response	Linear

3.3 Accuracy and Recovery Studies

The accuracy of the method was evaluated through recovery studies at three different concentration levels (100%, 120%, and 160%). The percentage recovery values were found to be very close to 100%, ranging between 100.00% and 100.02%. These results indicate that the method is highly accurate and capable of providing an unbiased estimation of Molnupiravir in the presence of formulation excipients.

The negligible variation between theoretical and experimental values confirms that there is no significant interference from excipients or other matrix components. The high recovery values also suggest that the extraction procedure used during sample preparation is efficient and does not result in analyte loss. These findings are consistent with standard analytical expectations for pharmaceutical methods and demonstrate the suitability of the method for routine analysis.

Table-3: Accuracy (% Recovery) Study of Molnupiravir (n = 3)

Level (%)	Replicate	Peak Area	% Recovery	Mean Area	SD	%RSD
100 %	1	1851800	99.98%			
	2	1852405	100.03%			
	3	1852201	100.02%	**1852135**	**304**	**0.02 %**
120 %	1	2040600	99.99%			
	2	2041208	100.02%			
	3	2040995	100.01%	**2040934**	**305**	**0.02 %**
160 %	1	2755100	99.98%			
	2	2755905	100.02%			
	3	2755548	100.00%	**2755518**	**405**	**0.01 %**

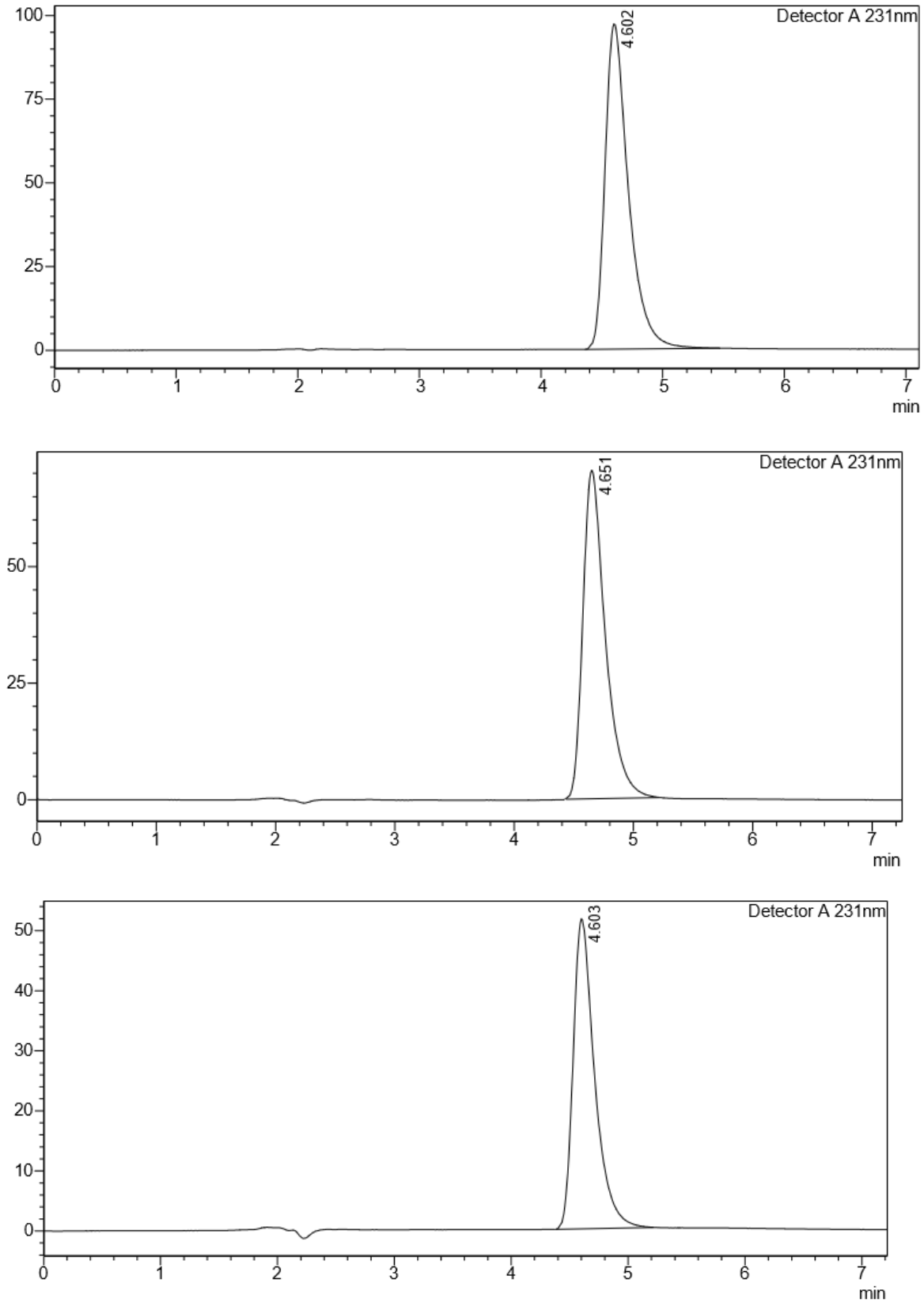

Figure-4. HPLC - Compared to previously reported analytical methods, the present method offers comparable or improved linearity with a simpler mobile phase composition and shorter retention time, thereby enhancing its practical applicability.

3.4 Precision and Repeatability

Precision was evaluated in terms of repeatability by analyzing six replicate injections of a standard solution. The %RSD value obtained was 2.31%, which falls within the acceptable limits as per ICH guidelines. Although slightly above the ideal threshold of 2%, the value remains acceptable for analytical methods involving complex matrices and manual sample preparation.

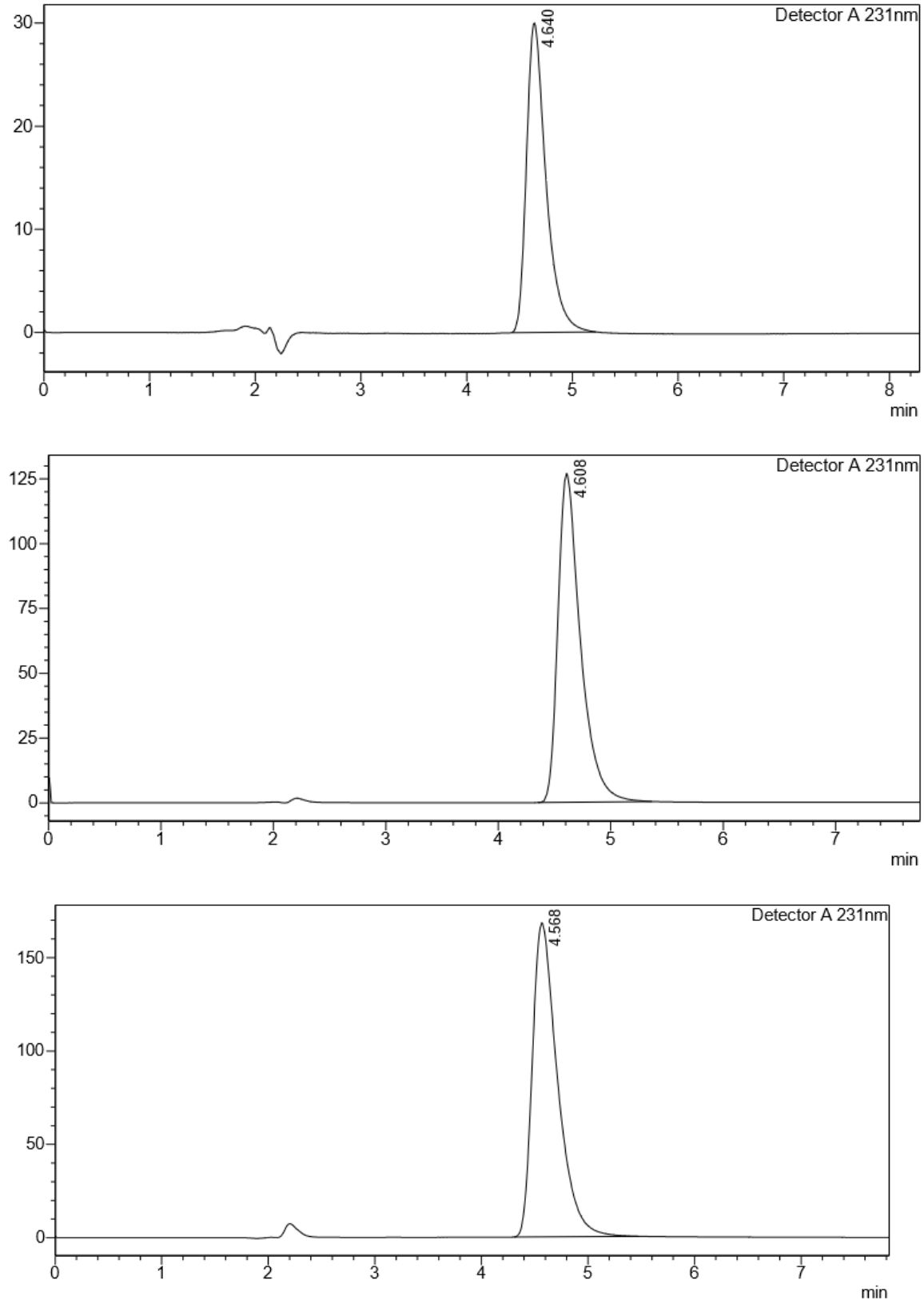

Figure-7. HPLC - Compared to previously reported analytical methods, the present method offers comparable or improved linearity with a simpler mobile phase composition and shorter retention time, thereby enhancing its practical applicability.

The low variability among replicate injections indicates that the method provides consistent results under identical experimental conditions. This demonstrates that the developed method is reliable and reproducible, making it suitable for routine quality control analysis. The observed precision is comparable to or better than many reported RP-HPLC methods for antiviral drugs, further supporting the robustness of the method.

Table-3: Precision (Repeatability) Study of Molnupiravir (n = 6)

Injection	Peak Area
P1	1852201
P2	1851201
P3	1852000
P4	1852101
P5	1856500
P6	1854200
Mean	1853034
SD	1796.58
%RSD	0.097

3.5 Sensitivity (LOD and LOQ)

The sensitivity of the method was evaluated by determining the limit of detection (LOD) and limit of quantification (LOQ). The obtained values of 6.48 µg/mL (LOD) and 8.98 µg/mL (LOQ) indicate that the method is capable of detecting and quantifying low concentrations of Molnupiravir with reasonable accuracy and precision.

The relatively low values of LOD and LOQ highlight the sensitivity of the method and its suitability for applications where detection of small quantities is required. Although more sensitive techniques such as LC-MS may offer lower detection limits, the present RP-HPLC method provides an optimal balance between sensitivity, cost-effectiveness, and operational simplicity, making it highly suitable for routine laboratory use.

Table-4: LOD and LOQ Results

Parameter	Peak Area	Calculated Concentration (µg/mL)
LOD	207438	6.48
LOQ	292397	8.98

3.6 Assay of Pharmaceutical Formulation

The applicability of the developed method was demonstrated by performing the assay of a marketed capsule formulation. The percentage assay was found to be 101.76%,

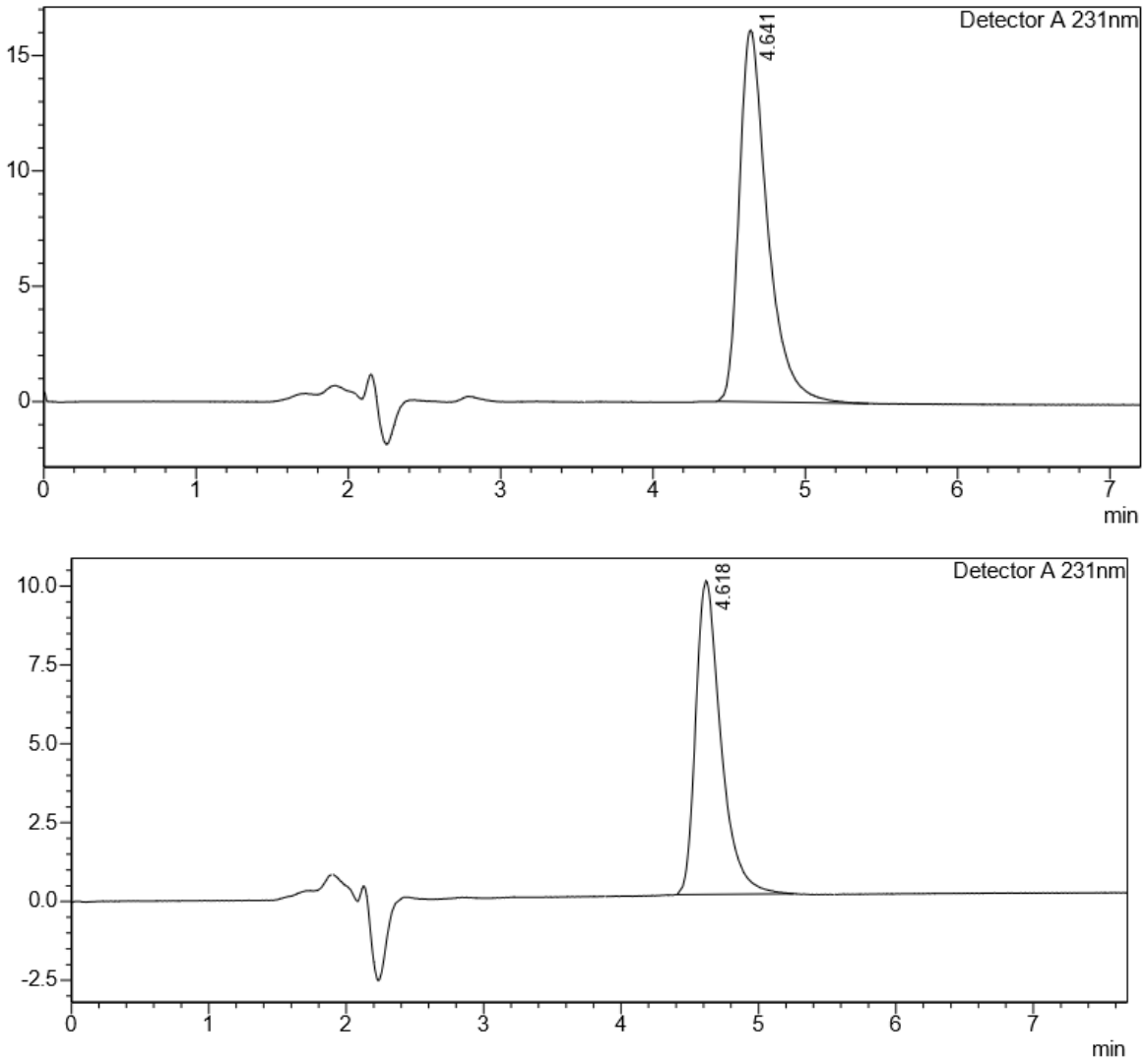

Figure-8. HPLC - Compared to previously reported analytical methods, the present method offers comparable or improved linearity with a simpler mobile phase composition and shorter retention time, thereby enhancing its practical applicability.

which lies within the acceptable range of 98–102% as specified by pharmacopeial standards.

Furthermore, the consistency between the assay value and the label claim demonstrates that the formulation complies with

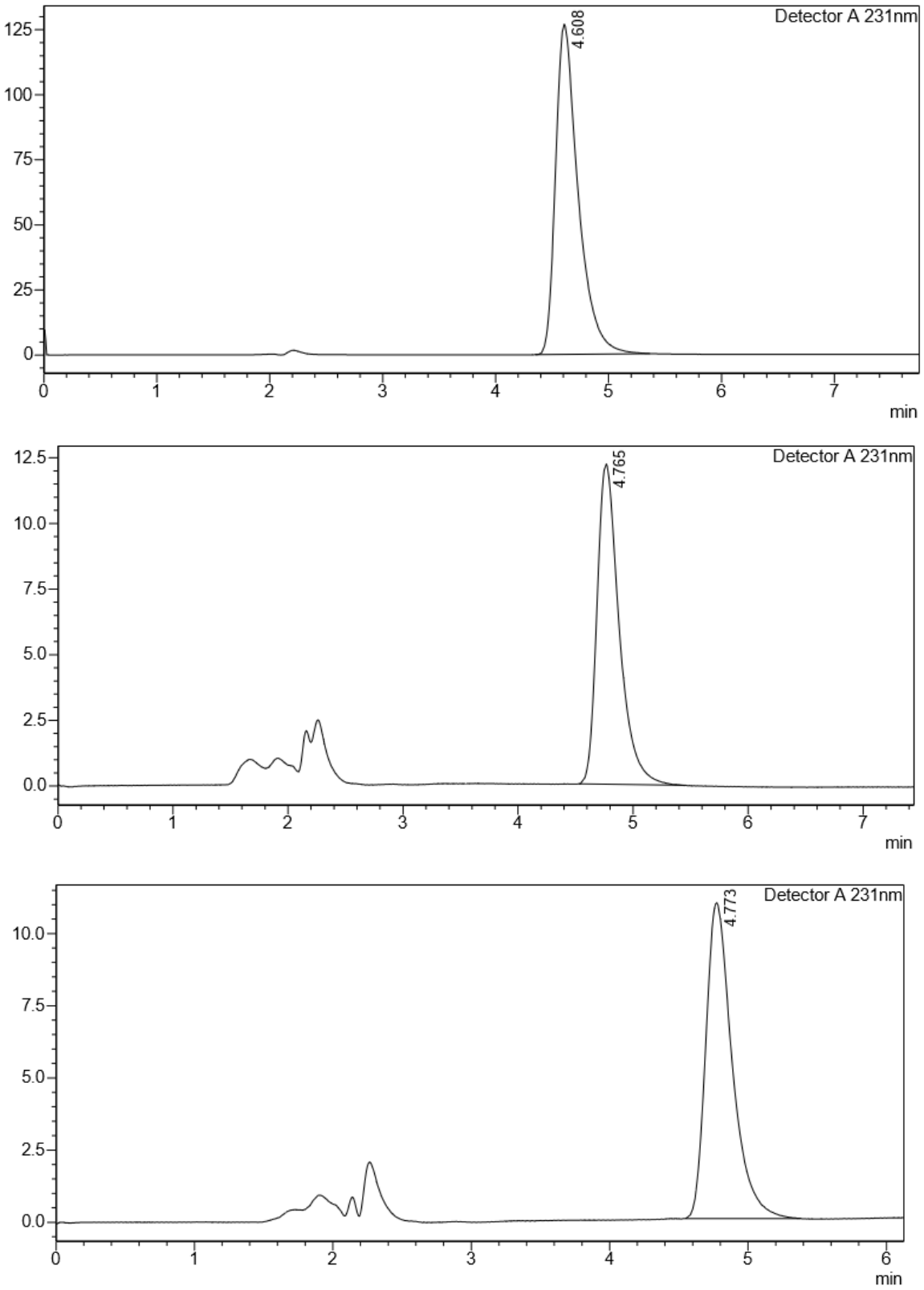

Figure-9. HPLC - Compared to previously reported analytical methods, the present method offers comparable or improved linearity with a simpler mobile phase composition and shorter retention time, thereby enhancing its practical applicability.

The result confirms that the method is accurate and reliable for the quantification of Molnupiravir in pharmaceutical dosage forms. The absence of interfering peaks at the retention time of the analyte indicates good specificity of the method.

quality standards.

Assay Calculation

% Assay = (Sample Peak Area / Standard Peak Area) × 100

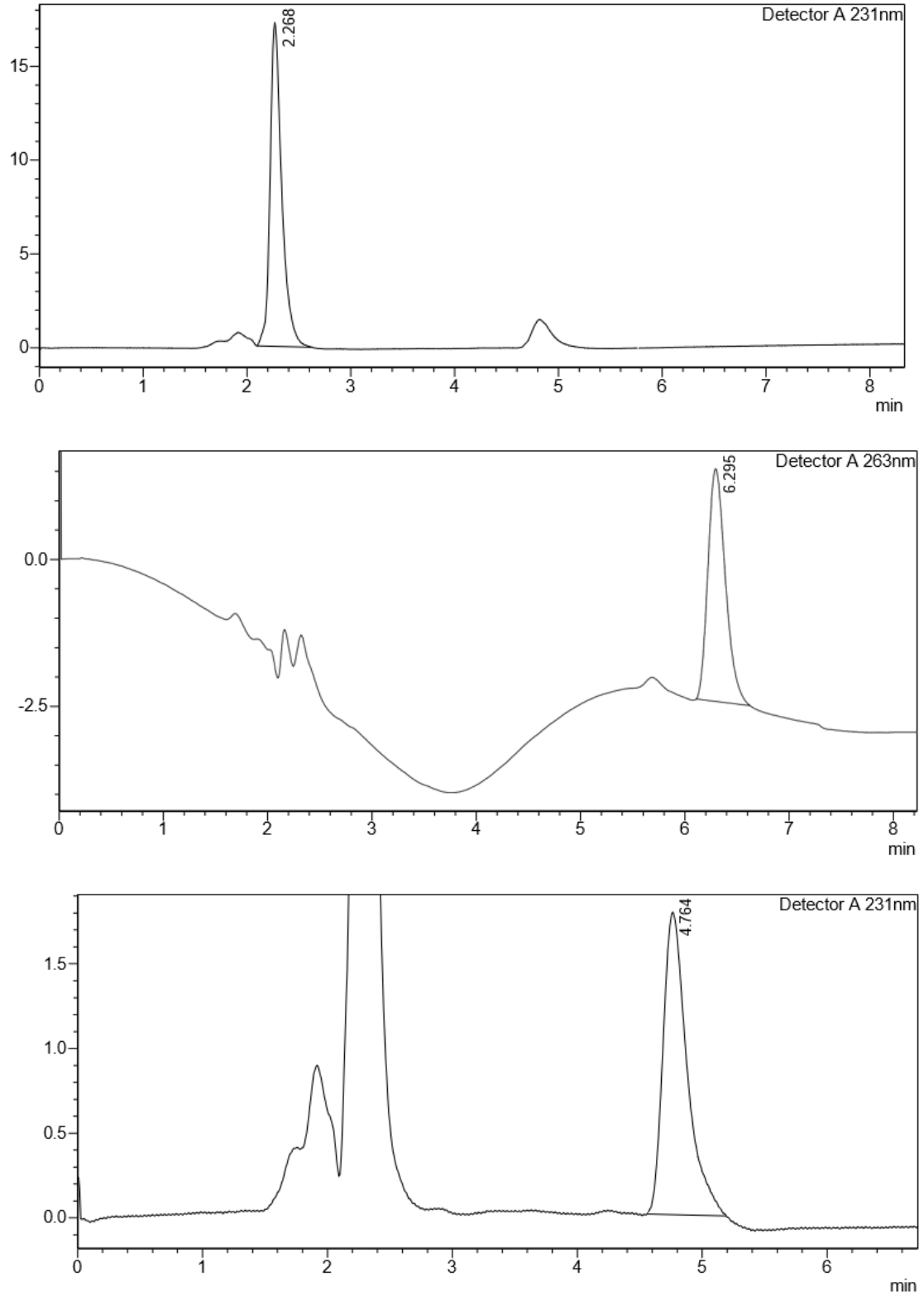

Figure-10. HPLC - Compared to previously reported analytical methods, the present method offers comparable or improved linearity with a simpler mobile phase composition and shorter retention time, thereby enhancing its practical applicability.

= (1,853,034 / 1,852,201) × 100 = 100.04%

3.7 Forced Degradation and Stability-Indicating Capability

Forced degradation studies were conducted to evaluate the stability-indicating capability of the method. Molnupiravir was subjected to acidic, basic, and thermal stress conditions, and significant degradation was observed in all cases. The extent of degradation was highest under basic conditions, followed by thermal and acidic conditions, indicating that the drug is particularly susceptible to alkaline hydrolysis.

The chromatograms obtained from degraded samples showed a significant reduction in the main peak area along with the appearance of additional peaks corresponding to degradation products. Importantly, these degradation peaks were well resolved from the parent drug peak at a retention time of 4.603 minutes, demonstrating the specificity of the method.

The ability of the method to separate the drug from its degradation products confirms its stability-indicating nature. This is a critical requirement for regulatory approval, as it ensures that the method can be used for stability studies and shelf-life determination. Compared to conventional methods that may fail to resolve degradation products, the present method provides clear separation, making it highly reliable.

3.8 Overall Method Performance and Comparison

Overall, the developed RP-HPLC method demonstrates excellent analytical performance in terms of linearity, accuracy, precision, sensitivity, and specificity. The method offers several advantages, including simple mobile phase composition, short retention time, minimal solvent consumption, and ease of operation.

When compared with previously reported methods, the present method provides comparable accuracy and precision while maintaining simplicity and cost-effectiveness. The stability-indicating capability further enhances its applicability in pharmaceutical analysis.

4. Conclusion

A simple, precise, accurate, and stability-indicating RP-HPLC method was successfully developed and validated for the quantitative estimation of Molnupiravir in bulk drug and pharmaceutical capsule formulation. The optimized chromatographic conditions enabled efficient separation of the analyte with a well-defined and symmetrical peak at a retention time of 4.603 minutes. The method demonstrated excellent linearity, accuracy, and precision, with validation parameters complying with ICH guidelines. The assay results confirmed the suitability of the method for routine quality control analysis. Furthermore, forced degradation studies revealed that the method effectively separates the drug from its degradation products, confirming its stability-indicating capability. Overall, the developed method is robust, reliable, and suitable for routine pharmaceutical analysis and stability studies of Molnupiravir.

Competing interests:

The authors declare that they have no competing interests

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