RESEARCH ARTICLE

Stability-Indicating RP-HPLC Method Development and Validation for Quantification of Molnupiravir in Bulk and Pharmaceutical Formulation

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ABSTRACT
The article presents the development and validation of a basic, precise, and versatile RP-HPLC technique for quantifying molnupiravir in bulk medication and capsule formulations. A Zodiac C18 column (150 × 4.6 mm, 5 µm) was used with an isocratic mobile phase comprising 15 mM ammonium acetate, acetonitrile, and methanol (70:20:10 v/v) at a flow rate of 0.8 mL/min. Detection occurred at 236 nm with a retention duration of 11.7 minutes. The technique was verified in accordance with ICH requirements for linearity, accuracy, precision, robustness, sensitivity, and system appropriateness. Linearity was detected throughout the range of 3.12–100 µg/mL, with a correlation value (R^2) of 0.9999. The LOD was determined to be 2.06 µg/mL, while the LOQ was established at 6.87 µg/mL. Forced degradation experiments revealed substantial breakdown in basic and oxidative environments, although the drug remained stable in acidic and photolytic settings. The suggested approach demonstrated suitability for regular quality control and stability assessments of molnupiravir in pharmaceutical formulations.

Keywords: Molnupiravir, RP-HPLC, Stability indicating method, Method validation, Forced degradation, ICH guidelines.
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INTRODUCTION

Molnupiravir, chemically designated as [(2R,3S,4R,5R) -3,4-dihydroxy-5-[(4Z)-4-(hydroxyimino)-2-oxo-1,2,3,4-tetrahydropyrimidin-1-yl]oxolan-2-yl Methyl 2-methylpropanoate is an orally bioavailable prodrug of the nucleoside analogue N4-hydroxycytidine. After being transmitted, it is swiftly metabolised to its active ribonucleoside triphosphate form, which is integrated into viral RNA by the viral RNA-dependent RNA polymerase. This integration leads to the buildup of mutations during viral replication, resulting in a "error catastrophe" that inhibits viral proliferation. Due to this unique mechanism, molnupiravir has extensive antiviral efficacy against several RNA viruses, including influenza, Ebola, and coronaviruses. It acquired notable importance during the COVID-19 pandemic, since it received emergency use authorisation in several countries for the treatment of mild-to-moderate SARS-CoV-2 infection in high-risk individuals[1-5].

The precise and dependable measurement of molnupiravir in both bulk and pharmaceutical formulations is essential for quality control, stability assessment, and regulatory adherence due to its therapeutic significance Nonetheless, the accessibility of analytical techniques for the regular assessment of molnupiravir is still limited. Although very sensitive, these approaches need advanced apparatus, significant expenses, and proficient operators, hence limiting their use in standard pharmaceutical analysis. Likewise, several documented chromatographic techniques are exclusive to certain formulations or lack thorough validation in accordance with worldwide standards. Therefore, a straightforward, reliable, and validated RP-HPLC technique is essential for the regular analysis of molnupiravir in both bulk and dose forms[6-9].

HPLC is regarded as the most dependable instrument for pharmaceutical analysis owing to its exceptional sensitivity, repeatability, and ability to isolate medicines from contaminants and degradation products. RP-HPLC is favoured for the majority of pharmaceutical substances because to its flexibility, user-friendliness, and capacity to accommodate molecules with varying polarity.

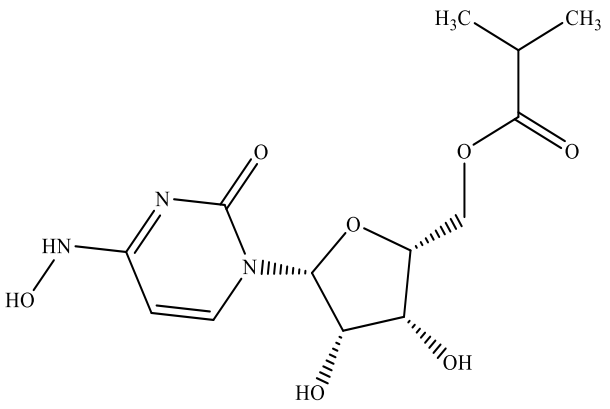

Figure 1: Chemical structure of Molupiravir

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Significantly, when developed as a stability-indicating assay technique (SIAM), RP-HPLC can differentiate the intact medication from its possible degradation products under stress circumstances, thereby offering essential insights into the stability profile of the medicinal material[10-12].

ICH standards stipulate that stability-indicating methodologies are essential for assessing the integrity and safety of APIs and pharmaceutical products. Forced degradation studies (FDS) in acidic, alkaline, oxidative, photolytic, and thermal conditions are crucial for evaluating the drug's vulnerability to environmental and chemical stressors[13,14]. These investigations facilitate the identification of degradation pathways and validate the specificity of the suggested analytical approach. The data for molnupiravir is especially significant due to its new entry into the pharmaceutical market, where detailed stability information remains under development.

This study aims to develop and validate a stability-indicating RP-HPLC technique for quantifying molnupiravir in bulk and capsule formulations.

The methodology was developed in compliance with ICH Q2(R1) recommendations, facilitating the assessment of essential validation parameters including specificity, linearity, precision, accuracy, robustness, LOD, and LOQ[15-17]. Furthermore, thorough forced degradation tests were conducted to examine the stability of molnupiravir under various stress settings and to ascertain the method's capability to separate degradation products from the intact medication.

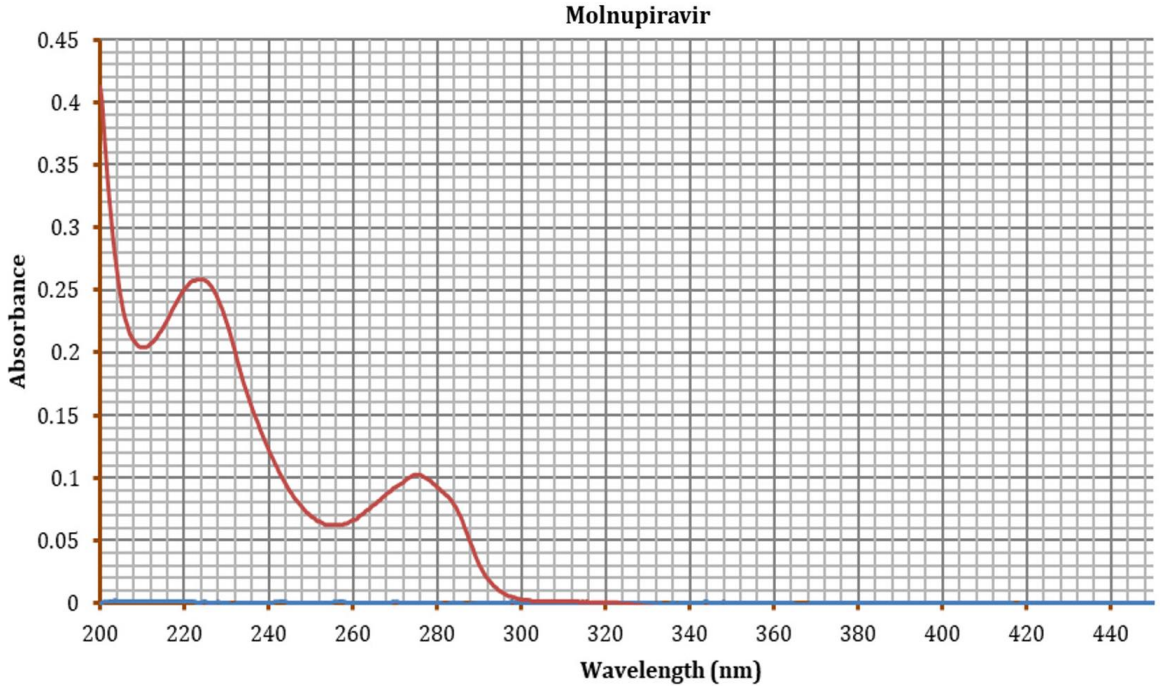

Figure 2: UV spectra of Molupiravir by UV Spectroscopy

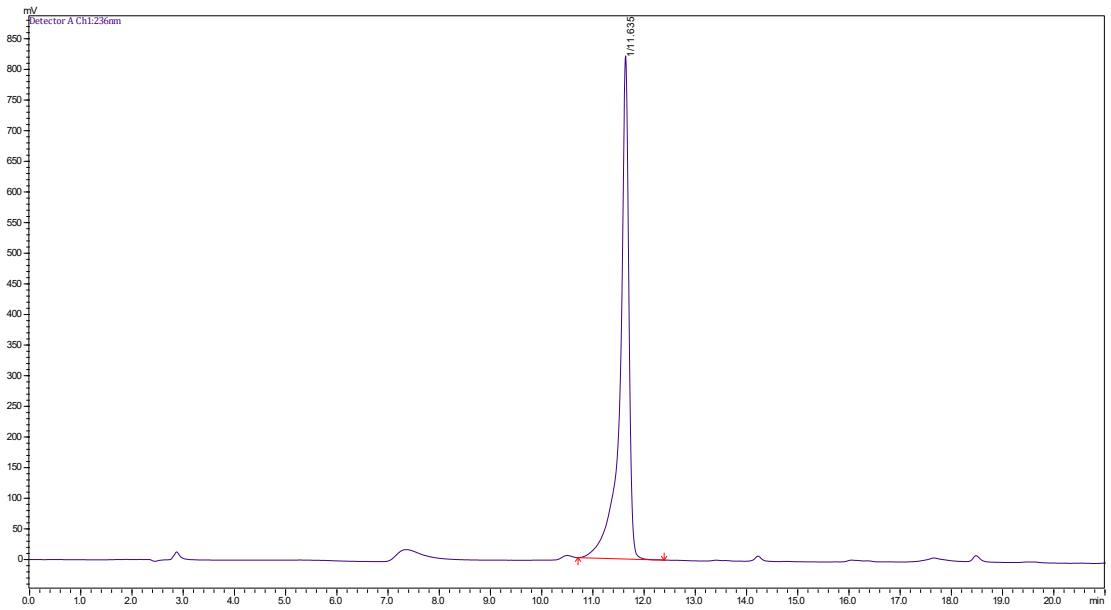

Figure 3: The optimized chromatogram of Molupiravir by developed method showed RT at 11.7 min

This work seeks to address the current deficiency by offering a proven, cost-effective, and dependable RP-HPLC technology suitable for regular use in quality control labs. The devised approach guarantees precise quantification of molnupiravir in pharmaceutical formulations while also providing essential stability data to assure its safe use and regulatory compliance.

MATERIALS AND METHODS

Chemicals and Reagents

The working standard of Molnupiravir (claimed potency 99.68%) was kindly supplied by Dhmetech Manufacturer, Mumbai. Commercially available Molnupiravir capsules (MOLAZ, 200 mg strength) were procured from the local pharmaceutical market for analysis. HPLC-grade methanol (Rankem), acetonitrile (Avra Synthesis Ltd.), and ammonium acetate were used as solvents and reagents during the chromatographic studies. Additionally, 0.45 µm nylon membrane filters (Axiva Sichem Pvt. Ltd.) were employed for sample filtration to ensure clarity and prevent particulate interference in the HPLC system. Milli-Q water, freshly prepared through a purification unit, served as the aqueous component throughout the analytical procedures. All chemicals and solvents utilized were of analytical or HPLC grade to maintain the accuracy and reproducibility of the method.

Instrumentation

The HPLC system employed in this study was equipped with a quaternary pump, an autosampler for precise sample introduction, a photodiode array (PDA) detector for multi-wavelength monitoring, and controlled through Empower-2 software for data acquisition and analysis. Chromatographic separation was achieved using a Zodiac C18 reversed-phase column (150 × 4.6 mm, 5 µm particle size), which provided efficient resolution and reproducibility. For wavelength optimization and detection of the analyte, a UV–Visible spectrophotometer (WATERS Alliance 2695) was utilized. Accurate weighing of all samples and reagents was carried out using a calibrated Sartorius analytical balance, ensuring precision in sample preparation. The pH of buffer solutions and mobile phase was adjusted and verified using a standardized digital pH meter to maintain consistency and reliability of the method.

Preparation of Mobile Phase and Diluent

Diluent was freshly prepared by mixing 15 mM ammonium acetate, acetonitrile, and methanol in the ratio of 70:20:10 (v/v). The same composition was employed as the mobile phase to ensure compatibility between the sample and chromatographic system. Prior to use, the mobile phase was subjected to filtration through a 0.45 µm membrane filter to eliminate any particulate matter, followed by sonication to degas the solution and enhance its stability during analysis.

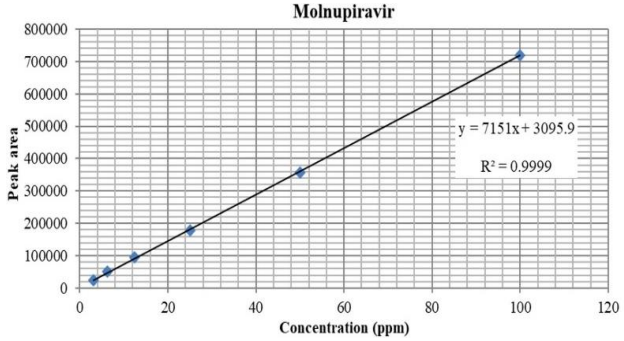

Figure 4: The calibration curve of Molnupiravir across the concentration range of 3.12–100 µg/mL

Table 1: Linearity and sensitivity parameters and results

Concentration (µg/mL)	Area
100	720107
50	358015
25	177301
12.5	95693
6.25	50544
3.125	24777
Regression Equation	y=7151x + 3095.6
Correlation coefficient (R^2)	0.9999
Std. error of intercept	2006.300268
Std. Dev. of intercept	4914.411927
LOQ	6.87 µg/ml
LOD	2.06 µg/ml

Selection of Detection Wavelength

A freshly prepared solution of molnupiravir (10 µg/mL) was subjected to UV spectrophotometric scanning in the range of 200–400 nm to determine its characteristic absorption profile[18-20]. The drug exhibited a prominent absorption peak at 236 nm, which was identified as the wavelength of maximum absorbance (λmax). Hence, this wavelength was chosen for subsequent analytical measurements, as it ensures higher sensitivity and reliability in quantification.

Preparation of Standard Solution

Approximately 10 mg of molnupiravir was precisely measured and placed to a volumetric flask where it was dissolved in the chosen diluent. The solution underwent sonication to achieve full dissolution, resulting in a clear solution of stock with a concentration of 1000 µg/mL. A series of appropriate dilutions were methodically made from the main stock using the same diluent to achieve the requisite working concentrations for further analysis.

Chromatographic Conditions

The chromatographic analysis was performed using a Zodiac C18 column (150 × 4.6 mm, 5 µm particle size). The mobile phase consisted of a mixture of 15 mM ammonium acetate, acetonitrile, and methanol in the ratio of 70:20:10 (v/v). The flow rate was maintained at 0.8 mL/min, and detection was carried out at a wavelength of 236 nm. The injection volume for each sample was 10 µL, and the total run time was 20 minutes, with the retention time of molnupiravir observed at 11.7 minutes.

Validation Parameters

The analytical method developed in this study was systematically validated in compliance with the ICH guidelines. The validation parameters included evaluation of linearity, accuracy, precision, and sensitivity, expressed in terms of the LOD and LOQ. In addition, system suitability tests and robustness studies were performed to ensure the reliability and reproducibility of the method under varying conditions. The method was further applied for the assay of the marketed formulation to confirm its practical applicability.

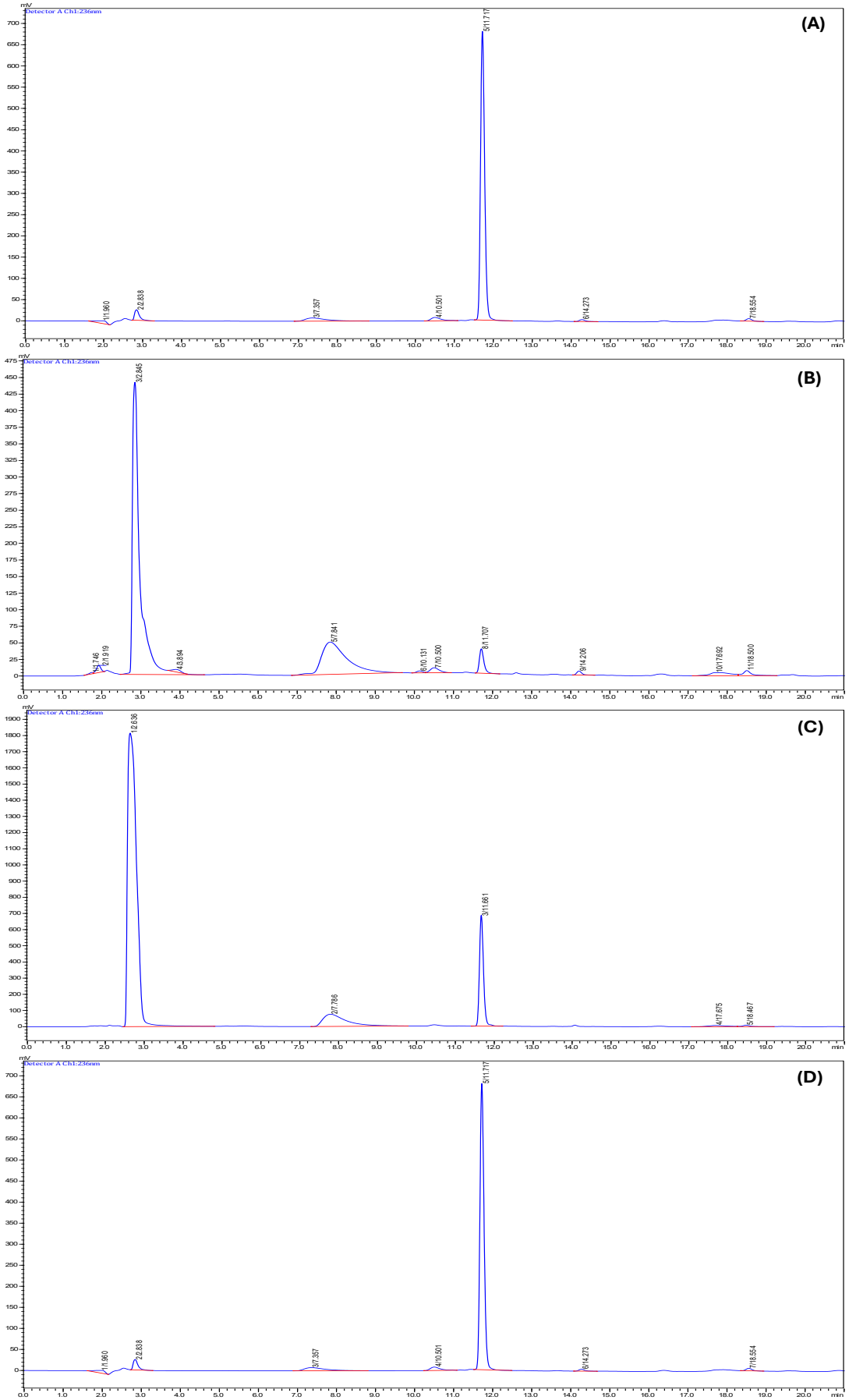

Figure 5: The chromatograms obtained through FDS: (A) Acid degradation; (B) Basic degradation; (C) Oxidative degradation; (D) Photolytic degradation

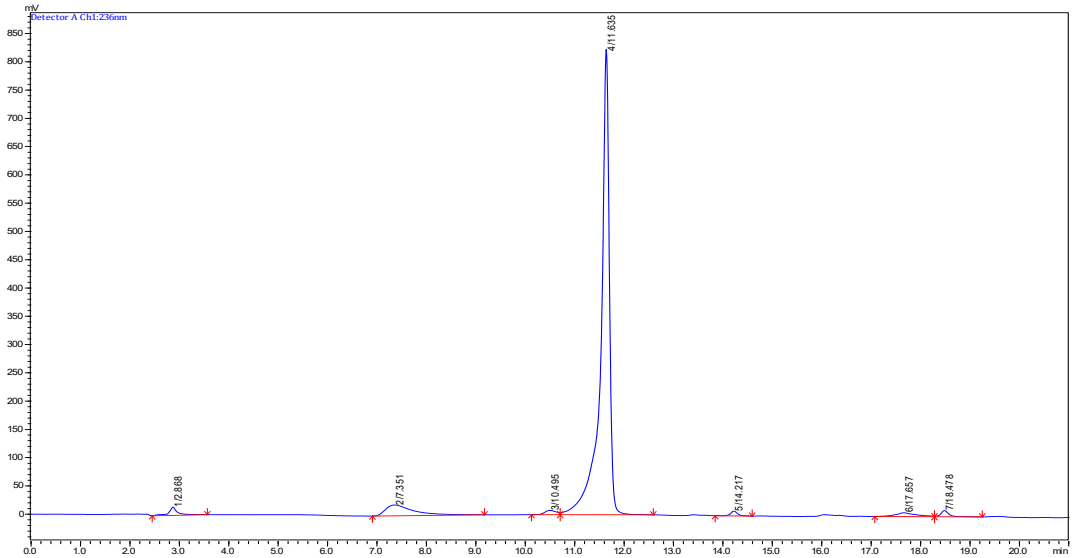

Figure 6: The chromatogram of molnupiravir obtained from marketed formulation by applying developed method

Forced Degradation Studies (FDS)

Accelerated stability studies were performed by subjecting 100 µg/mL solutions of molnupiravir to different conditions[15,21].

Acidic and Basic Degradation

10 millilitres of 0.1N hydrochloric acid and sodium hydroxide were used to reflux and evaporate 100 µg/mL of molnupiravir for one hour at 70 °C in a water bath. The same quantity was then let to cool to ambient temperature in HCl. Subsequent to this duration, each solution was filtered, neutralised, and its volume was reconstituted with diluent to attain a concentration of 40 µg/mL.

Oxidative Degradation

100 µg/mL of molnupiravir was refluxed with 3% hydrogen peroxide for 30 minutes at 70 °C in a water bath and then evaporated. The solution was then filtered and adjusted to a final volume using diluent to achieve a concentration of 40 µg/mL.

Photolytic Degradation

10 millilitres of a 100 ppm molnupiravir solution was exposed to UV light for one day. A concentration of 40 µg/mL was prepared using a diluent and then injected for analysis.

RESULTS AND DISCUSSION

Selection of Wavelength and Mobile Phase

The UV spectrophotometric scan of the drug exhibited maximum absorbance at 236 nm (Figure 2), which was therefore selected as the detection wavelength for subsequent analysis. Among the various mobile phase combinations evaluated, a mixture of 15 mM ammonium acetate, acetonitrile, and methanol in the ratio of 70:20:10 (v/v) was found to be most suitable, as it produced sharp, well-defined, and symmetrical peaks with satisfactory resolution. Under these optimized chromatographic conditions, the compound demonstrated a consistent retention time of approximately 11.7 minutes (Figure 3), confirming the suitability and reproducibility of the developed method.

Method Validation

Linearity and Sensitivity

The calibration curve exhibited a well-defined linear relationship within the concentration range of 3.12–100 µg/mL, demonstrating high reliability for quantitative analysis. The correlation coefficient (R^2 = 0.9999) confirmed the excellent linearity of the method (Figure 4). The obtained regression equation, y = 7151x + 3095.6, clearly established the direct proportionality between the peak area and the corresponding drug concentration, thereby ensuring the suitability of the method for precise estimation of the analyte (Table 1).

LOD and LOQ

The sensitivity of the optimized RP-HPLC method was evaluated by determining the LOD and LOQ. These parameters were assessed by injecting a series of progressively lower concentrations of the standard drug solution under the established chromatographic conditions. The LOD and LOQ were calculated based on the signal-to-noise ratio, which ensures reliable detection and accurate quantification at minimal concentrations. The method exhibited an LOD of 2.06 µg/mL and an LOQ of 6.87 µg/mL, indicating its high sensitivity and suitability for precise analytical applications (Table 1).

Repeatability Studies

The repeatability research included the injection of six duplicate preparations of molnupiravir (100 µg/mL) under optimised chromatographic conditions (Table 2). The results demonstrated excellent reproducibility, with %RSD for peak areas found to be less than 2%, it is well within the allowed parameters established by ICH standards. The consistency in retention time (11.7 min) across injections confirmed the stability of chromatographic conditions, while the high number of theoretical plates (33,502) reflected superior column efficiency. Additionally, the tailing factor (0.694) indicated a sharp and symmetrical peak, ensuring accurate peak integration and quantitation. Adequate resolution values further validated that the drug peak was well separated from any potential impurities or noise, consequently improving the method's dependability.

Precision

Table 2: The results of repeatability studies on developed method

Peak#	Ret. Time	Height	Area	Area%	T.Plate#	Tailing F.	Resolution	k'	Separation
1	2.885	8724	123839	0.7543	1622.905	1.004	--	0	0
2	7.325	144981	6012051	36.6192	1023.832	2.884	7.386	1.539	0
3	10.533	6650	101995	0.6213	9880.233	1.175	4.79	2.651	1.723
4	11.737	860222	10070945	61.3418	33502.37	0.694	3.539	3.068	1.157
5	14.254	4839	46449	0.2829	55327.29	1.423	10.09	3.94	1.284
6	18.568	5572	62464	0.3805	66981.01	1.26	16.299	5.436	1.379

The intraday and interday precision experiments further validated the dependability of the established technique (Table 3). For intraday analysis, six duplicates of molnupiravir at 100 µg/mL were assessed on the same day, yielding %RSD values between 0.31 to 1.34.

Interday precision conducted on three successive days produced %RSD values ranging from 0.30 to 0.71. All findings were comfortably below the ICH acceptance threshold of no more than 2%, validating that the procedure is both repeatable and consistent over time. The little fluctuation in peak area and retention duration indicates superior instrument performance and the durability of the chromatographic conditions, confirming the method's appropriateness for regular quality control assessment.

Accuracy

Accuracy was evaluated using recovery trials at three concentration levels (100%, 120%, and 150% of the target concentration, as shown in Table 4). The recovery percentage of molnupiravir ranged from 99.9% to 102.5%, with mean recovery values approximately around 101%. The very low standard deviation and %RSD values (<0.3) signify little variation across replicates, hence affirming the method's correctness.

These findings clearly demonstrate that the proposed RP-HPLC method can reliably quantify molnupiravir without interference from excipients present in the formulation, thereby proving its applicability for assay of both bulk drug and finished product.

System Suitability

The system suitability metrics, including theoretical plates (33,502), capacity factor (3.068), and tailing factor (0.694), conformed to ICH approval standards, hence confirming the efficiency in the chromatographic process (Table 5).

Robustness

Method robustness was assessed by introducing slight variations in flow rate (±0.2 mL/min) and mobile phase composition (±5% organic modifier). These adjustments did not cause notable shifts in retention time, peak area, resolution, or tailing factor, and all system suitability parameters stayed within acceptable limits. This confirms the method's resilience to minor operational changes, ensuring consistent performance across laboratories and experimental conditions.

FDS

FDS were conducted to evaluate the stability-indicating characteristics of the new RP-HPLC technique (Table 6). Under acidic (0.1 N HCl) and photolytic conditions, molnupiravir remained stable with no detectable degradation peaks, suggesting resistance to these stressors. In contrast, substantial deterioration was seen under alkaline conditions (0.1 N NaOH) and oxidative (3% H_2O_2) conditions, where two and three degradation products were formed, respectively, corresponding to ~89% and ~72% degradation. Importantly, the molnupiravir peak remained well resolved from its degradation products in all conditions, confirming specificity of the method. These results establish that the method is capable of distinguishing molnupiravir from its degradants, thereby qualifying it as a true stability-indicating assay suitable for stability testing and shelf-life prediction studies. The chromatograms obtained through FDS are depicted in Figure 5.

Table 3: Intraday and interday precision data from developed method

S. No.	Concentration (ppm)	Area	Average	Std. Deviation	%RSD
		Intraday			
1	100 ppm	603596 619639 614388	612541	8179.43	1.34
2	100 ppm	609301 612600 609344	610415	1892.39	0.31
3	100 ppm	613144 612655 605453	610417	4306.19	0.71
	Range of % RSD				0.3 - 1.34
		Interday			
Day 1	100 ppm	613144 612655 605453	610417	4306.19	0.71
Day 2	100 ppm	619035 615997 619437	618156	1880.81	0.30
Day 3	100 ppm	619127 610159 611427	613571	4853.23	0.79
	Range of % RSD				0.30 - 0.71

Evaluation of Commercial Formulation

The assay of the commercial capsule formulation (MOLAZ, 200 mg) was performed using the developed method. The amount of molnupiravir present was calculated to be 100.6% of the label claim, which is within pharmacopeial acceptance limits (±2%). The chromatograms showed absence of interfering peaks during the retention time of molnupiravir (Figure 6), thereby confirming the specificity of the method. This result not only supports the accuracy of the method in real pharmaceutical matrices but also underscores its suitability for routine batch analysis in quality control laboratories.

Table 4: Accuracy studies

% Level	Std. Spiked (mL)	Amount recovered (%)	% Recovery	Mean % Recovery	± SD	%RSD
100	0	101.18	100%			
100	0	101.14	99.99%	100%	0.0252	0.0252
100	0	101.19	101.02%			
120	4	123.27	101.72			
120	4	123.56	102.5%	101.06%	0.2276	0.2276
120	4	123.83	102.08%			
150	8	133.75	101.9			
150	8	133.42	101.62	101.42%	0.1799	0.1799
150	8	133.65	101.89			

Table 5: Parameters and outcomes of system suitability

System suitability parameters	Results	Acceptable Values
Theoretical plates (*N*)	33502	> 2000
Capacity Factor (*K'*)	3.068	> 0.5 - <10
Resolution (*R*)	---	≥ 2
Selectivity/Separation factor (α)	1.157	> *k'*
Asymmetry/Tailing factor (*T*)	0.694	> 2
Retention time (t_R)	11.73 min	> *k'*
Wavelength of Detection (nm)	236 nm	> 200 nm
Repeatability (%RSD)	0.71	< 2
Intra-Day Precision (%RSD)	0.31-1.34	< 2
Inter-Day Precision (%RSD)	0.30 -0.71	< 2
Linearity range	3.13 – 100 µg/ml	NA
Regression equation	y=7151x + 3095.6	NA
SE of intercept (S_e)	2006.300268	NA
SD of intercept (S_a)	4914.411927	NA
Correlation Coefficient (r^2)	0.9999	NA
LOQ (µg/mL)	6.87 µg/ml	NA
LOD (µg/mL)	2.06 µg/ml	NA

Table 6: FDS to assess the stability-indicating nature of the developed RP-HPLC method

Conditions	RT	RT (after degradation)	No. of degradants	% degradation
Acid (0.1N/M HCl)	11.7	11.7	0 degradants	0%
Base (0.1N/M NaOH)		2.845	2 degradants	89%
Oxidation (3 % H_2O_2)		2.75	3 degradants	72%
Photodegra-dation 24 hr		11.7	0 degradant	0%

The developed RP-HPLC method provides a reliable approach for quantitative estimation of molnupiravir in both bulk and capsule formulations. The linearity and sensitivity data confirm that the method is suitable for detecting low concentrations, making it applicable for trace-level impurity profiling. The accuracy and precision results validate reproducibility and reliability, which are critical for quality control. FDS revealed that molnupiravir is stable under acidic and photolytic conditions but highly susceptible to degradation under alkaline and oxidative stress. This information is crucial for designing appropriate storage and formulation strategies. Compared to previously reported analytical techniques such as LC-MS/MS, this method is cost-effective, less resource-intensive, and practical for routine laboratory use.

CONCLUSION

An easy, accurate, and stability-indicating RP-HPLC technique was effectively designed and validated for the quantitative assessment of molnupiravir in bulk and capsule formulations.

The approach satisfied ICH validation requirements, affirming its dependability for linearity, sensitivity, accuracy, precision, robustness, and system applicability. Forced degradation experiments confirmed its specificity by displaying the capacity to differentiate the drug from its breakdown products, with molnupiravir exhibiting significant disintegration under alkaline and oxidative stress, but maintaining stability in acidic and photolytic environments. The analysis of the commercial formulation further validated its use in actual pharmaceutical matrices. The suggested approach is very ideal for regular quality control and stability investigations of molnupiravir due to its accuracy, repeatability, and cost-effectiveness.

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