ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26jan730

A Comprehensive Review of Analytical Methods for the Determination of Molnupiravir

Risha A. Chaudhary[1]; Dr. Pruthviraj K. Chaudhary[2]; Dr. Khushbu Patel[3]; Dr. C. N. Patel[4]

[1,2,3,4]Pharmaceutical Quality Assurance Shri Sarvajanik Pharmacy College, Near Arvind Baug Mehsana-1, Gujarat, India

Publication Date: 2026/02/02

Abstract: Viruses can replicate only within living host cells, as they depend entirely on cellular machinery for their multiplication. According to the type of nucleic acid they contain, viruses are categorized as DNA or RNA viruses. Antiviral medications are developed to suppress viral replication and are classified into agents active against retroviruses and those effective against non-retroviral infections. Although most antiviral drugs are virus-specific, a few demonstrate activity against a wider range of viruses. Molnupiravir is a recently introduced orally administered antiviral agent that is effective against select RNA viruses by disrupting the process of viral RNA synthesis.

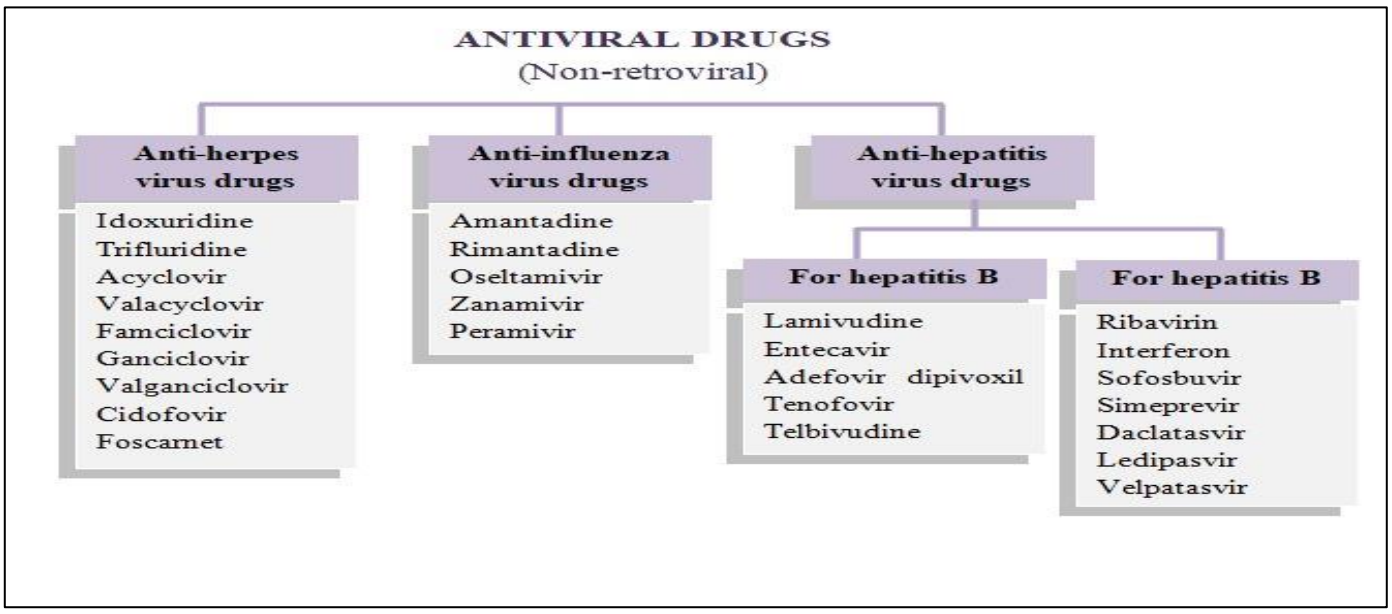
Keywords: *Molnupiravir, Anti-Viral, Development and Validation, HPLC.*

How to Cite Risha A. Chaudhary; Dr. Pruthviraj K. Chaudhary; Dr. Khushbu Patel; Dr. C. N. Patel (2026) A Comprehensive Review of Analytical Methods for the Determination of Molnupiravir. *International Journal of Innovative Science and Research Technology*, 11(1), 2518-2521. https://doi.org/10.38124/ijisrt/26jan730

I. INTRODUCTION

➢ *Introduction of Antiviral [1-3]*

Antiviral agents are pharmacological substances employed in the management of viral infections. The majority of these drugs are designed to act against specific viral pathogens, although certain agents possess broad-spectrum activity against multiple viruses. Viruses are extremely small infectious entities that contribute substantially to global disease burden and mortality. They are biologically active only within host cells, as they rely entirely on the host's cellular machinery for genome replication and protein synthesis, which is why they are classified as obligate intracellular parasites. Based on the nature of their nucleic acid, viruses are broadly categorized into DNA viruses and RNA viruses. Antiviral agents are classified into two broad categories namely non retroviral drugs and retroviral drugs. This classification is based on the type of virus they target and further they are classified based on particular viral disease they cause.



ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26jan730

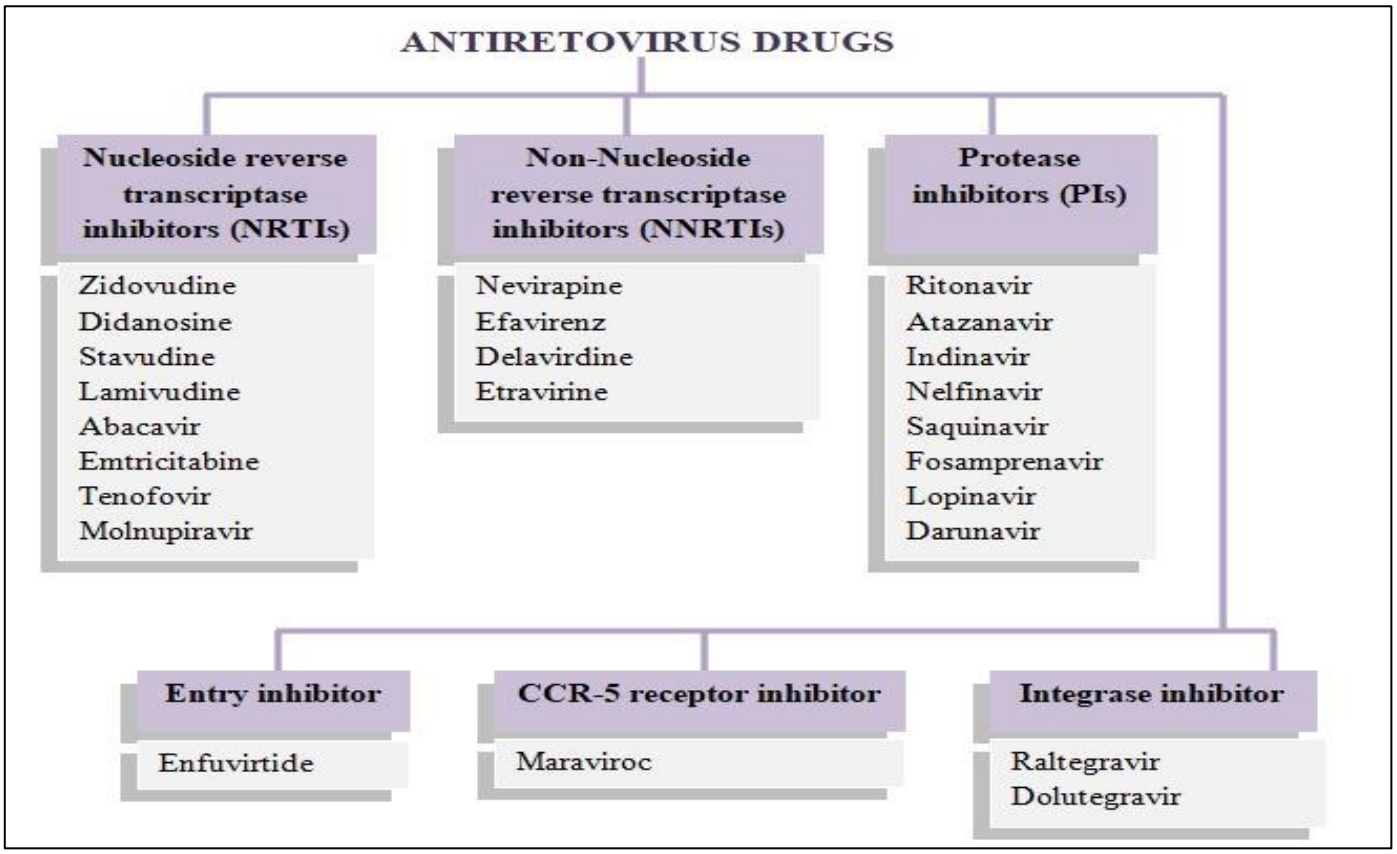


Fig 1 Classification of Antiviral Drug

➢ *Introduction of Molnupiravir [4-6]*

Molnupiravir**,** commercially available as Lagevrio, is an orally administered antiviral agent used in the treatment of infections caused by selected RNA viruses. It functions as a prodrug of the synthetic ribonucleoside analogue N4-hydroxycytidine. After metabolic activation, molnupiravir interferes with viral genome replication by inducing mutations in viral RNA, ultimately suppressing viral multiplication.

- *Mechanism of Action*

Molnupiravir is a prodrug of N-hydroxycytidine (NHC), which has broad antiviral activity. After entering the host cell, it is converted into its active form, NHC triphosphate. This active form competes with natural nucleotides during viral RNA synthesis and is incorporated into the viral RNA by the viral RNA-dependent RNA polymerase. NHC can behave like more than one natural base, which leads to incorrect base pairing during replication. Unlike drugs that stop RNA chain growth, molnupiravir allows RNA synthesis to continue. However, the newly formed viral RNA contains many errors, and these mistakes accumulate in later replication cycles. As a result, the virus produces defective and non-infectious particles that are unable to survive.

- *Drug Profile*

Molnupiravir is a synthetic nucleoside analogue derived from N (4)-hydroxycytidine, in which the 5′-hydroxyl group is chemically modified with a 2-methylpropanoyloxy moiety. The compound has the molecular formula $C_{13}H_{19}N_3O_7$ and a molecular weight of approximately 329.3 g/mol. It is a recently developed antiviral agent with a partition coefficient (log P) ranging from −1.1 to 0.8 and a dissociation constant (pKa) of about 8.2. Molnupiravir appears as a white to off-white solid with a melting point between 156 °C and 157 °C. It is soluble in water and readily dissolves in organic solvents such as methanol. Clinically, molnupiravir is administered orally at a dose of 800 mg (four 200 mg capsules) every 12 hours for a duration of five days, and it may be taken with or without food.

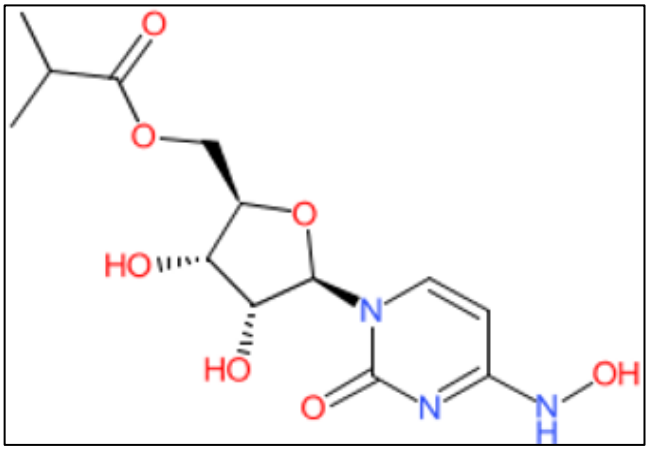


Fig 2 Structure of Molnupiravir

II. REVIEW OF LITERATURE [7-17]

➢ *Official Reported Method is not Reported as Per Any Pharmacopeia.*

ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26jan730

- *Reported Method*

Table 1 Reported Method for Assessment of Molnupiravir

Sr. No.	Title	Description	Ref No.
UV- SPECTROSCOPY			
1	Development and Validation of UV Method for Routine Analysis of Molnupiravir.	Solvent: Methanol Wavelength: 238 nm Linearity: 2-20 µg/mL	7
2	Uv visible spectroscopy method development and validation for estimation of Molnupiravir in solid dosage form.	Solvent: Water Wavelength: 280 nm Linearity:0.2-1 µg/mL	8
3	New UV Spectrophotometric Method for the Estimation of Molnupiravir used in the treatment of COVID-19.	Solvent: Methanol Wavelength: 236 nm Linearity: 10-50 µg/mL	9
HIGH PERFORAMCE LIQUID CHROMETOGRAPHY			
3	Development and validation of Molnupiravir assessment in bulk powder and pharmaceutical formulation by the RP-HPLC-UV method**.**	Stationary phase:C_{18} column (150 × 4.6 mm, 5 µm) Mobile phase: Buffer (pH 4.5): Methanol (70:30% v/v) Flow rate: 1 mL/min Wavelength: 236 nm	10
4	New analytical method development and validation for estimation of Molnupiravir in bulk and tablet dosage form by RP-HPLC method.	Stationary phase:C_{18} column (150 × 4.6 mm, 5 µm) Mobile phase: Methanol: Phosphate Buffer (pH 4.2) (35:65% v/v) Flow rate: 1 mL/min Wavelength: 236 nm	11
9	A validated stability indicating RP-HPLC method for the determination of Molnupiravir in pharmaceutical dosage form.	Stationary phase: C_{18} column (250 × 4.6 mm, 3.6 µm) Mobile phase: Orthophosphoric acid: Acetonitrile (60:40% v/v) Flow rate: 1 mL/min Wavelength: 254 nm	12
10	A stability indicating RP-HPLC method for determination of the COVID-19 drug Molnupiravir applied using nano formulations in permeability studies.	Stationary phase:C_{18} column (75 × 4.6 mm, 3 µm) Mobile phase: Acetonitrile: Water (20:80% v/v) Flow rate: 0.5 mL/min Wavelength: 240 nm	13
11	New Stability Indicating RP-HPLC Method for Estimation of the Drug Molnupiravir.	Stationary phase: C_{18} column (250 × 4.6 mm, 0.5 µm) Mobile phase: Acetonitrile: Methanol: Water (20:50:30%v/v/v) Flow rate: 1 mL/min Wavelength: 236 nm	14
12	Rp-HPLC method development and validation of Molnupiravir in bulk and its pharmaceutical dosage form.	Stationary phase: C_{18} column (150 × 4.6 mm, 5 µm) Mobile phase: Acetonitrile: Potassium dihydrogen phosphate buffer (pH 2.8) (25:75% v/v) Flow rate: 1 mL/min Wavelength: 220 nm	15
HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY			
5	Stability Indicating HPTLC Method of Molnupiravir and Comparative Study of Degradant with Marketed Molnupiravir Impurity- A.	Stationary phase: Silica gel HPTLC F_{254} plates Mobile phase: Toluene: n-Butanol: Methanol: Water developing system (5:3:1.5:0.5 % v/v) Wavelength: 276 nm	16
6	Simple Green Spectrophotometric & Chromatographic Assay of the Oral Antiviral Treatment of COVID-19: Molnupiravir -EIDD-2801.	Stationary phase: Silica gel-60 Mobile phase: Methanol: Glacial acetic acid (10:0.05 % v/v) Wavelength: 233 nm	17

III. CONCLUSION

The article reviews antiviral drugs, focuses on molnupiravir as an orally administered antiviral, and outlines the development and validation of an HPLC method for measuring molnupiravir in pharmaceutical dosage forms using a Quality by Design approach. By combining a detailed drug profile and literature survey with QbD principles, the work aims to create a reliable, precise, and robust analytical method suitable for routine quality control of molnupiravir products.

ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26jan730

REFERENCES

[1]. Sharma HL, and Sharma K, In Pharmacology, 3rd ed., Sharma & Sharma's Paras medical Publisher, Hyderabad, 2017, pp 789.

[2]. Karan W, Lippincott Illustrated Reviews Pharmacology, 6th ed., Tata McGraw Hill Publishing Company Limited, New Delhi, 1993, pp 536.

[3]. KD Tripathi, In Medical Pharmacology, 8thEd., KDT Jaypee brothers, 2019, pp 849, 861.

[4]. B.A. Jayk, M.M. Gomes, D.B. Musungaie, E. Kovalchuk, A. Gonzalez and V.D. Reyes, "Molnupiravir for oral treatment of COVID-19 in nonhospitalized patients," N. Eng. J. of Med., vol. 386(6), pp. 509-520, Dec 2021.

[5]. B.M. Maas, J. Strizki, R.R. Miller, S. Kumar, M. Brown and M.G. Johnson, "Molnupiravir: Mechanism of action, clinical, and translational science,", Clin. Transl. Sci., vol. 17(2), pp. 1-8, Feb 2024.

[6]. DrugBank, "Molnupiravir: Uses, Interactions, Mechanism of Action,", Sep 2025. https://go.drugbank.com/drugs/DB15661?utm_source=chatgpt.com

[7]. S. Islam, N.J. Fariha, S. Ahmed, O. Faruk and S.S. Rouf, "Development and Validation of UV Method for Routine Analysis of Molnupiravir," Bang. Pharm. J., vol. 28(1), pp. 83-93, Jan 2025.

[8]. B. Parmar, A. Raj, A. Vasava, V. Chauhan, M. Dalwadi and U. Upadhyay, "Uv Visible Spectroscopy Method Development and Validation for Estimation of Molnupiravir in Solid Dosage Form," Int. J. of Crea. Res. Tho., vol. 10(4), pp. 812-821, April 2022.

[9]. M. Deshpande, F. Shaikh, "New UV Spectrophotometric Method for the Estimation of Molnupiravir used in the treatment of COVID-19," The Open COVID J., vol. 4, pp. 21-29, March 2023.

[10]. A.M. Annadi, N. M. Elzahar, N.A. Abdel-Sattar, E.H. Mohamed, S.A. Mahmoud and M.S. Attia, "Development and validation of Molnupiravir assessment in bulk powder and pharmaceutical formulation by the RP-HPLC-UV method," R. Soci. of Chem., vol. 85(4), pp. 903-911, 2025.

[11]. S. Gandu, K.S. Gandla, and L. Repudi, "New analytical method development and validation for estimation of Molnupiravir in bulk and tablet dosage form by RP-HPLC method," Cell. Mol. Biomed. Rep., vol. 3(3), pp. 130-136, Sep 2023.

[12]. G. Kumaraswamy, "A validated stability indicating RP-HPLC method for the determination of Molnupiravir in pharmaceutical dosage form," Wo. J. of Adv. Res. and Rev., vol. 15(01), pp. 580–590, July 2022.

[13]. T. Recber, S.S. Timur, S.E. Kablan, F. Yalcin, T.C. Karabulut and R.N. Gursoy "A stability indicating RP-HPLC method for determination of the COVID-19 drug Molnupiravir applied using nano formulations in permeability studies," J. of Pharma. and Bio. Ana., vol. 214, pp. 1-8, May 2022.

[14]. M. Deshpande, F. Shaikh, V. Sable and K. Patil, "New Stability Indicating RP-HPLC Method for Estimation of the Drug Molnupiravir," Int. J. of Pharma. Qua. Ass., vol. 14(1), pp. 149-158 March 2023.

[15]. S. Akula, M. Sukanya, S. Naga, K.P. Kumar, N. Boggula, and D. Suchirea, "RP-HPLC Method Development and Validation of Molnupiravir in Bulk and Its Pharmaceutical Dosage Form," Biochem. and Cell. Archives., vol. 25(1), pp. 311, Jan 2025.

[16]. M.S. Tekade and P.M. Patil, "Stability Indicating HPTLC Method of Molnupiravir and Comparative Study of Degradant with Marketed Molnupiravir Impurity- A," Ira. J. of Ana. Chem., vol. 9(2), pp. 51-57 Sep 2022.

[17]. M.A. Moneim, M. Kamal, and M. Hamdy, "Simple Green Spectrophotometric & Chromatographic Assay of the Oral Antiviral Treatment of COVID-19: Molnupiravir." Egypt. J. of Chem., vol. 66(3), pp. 125-131, March 2023.