RESEARCH ARTICLE

Analytical Method Development and Validation of Remdesivir and Griseofulvin in API and its Dosage Form by RP-HPLC

Rakam Gopi Krishna[1*], Kadagoni Pravalika[2], Ramesh Konda[2], V A N V Harita[1], G Haritha[2]

[1]*Department of Pharmaceutical Chemistry, Marri Laxman Reddy Institute of Pharmacy, Dundigal, Hyderabad, Telangana, India-500043*
[2]*Department of Pharmaceutical Analysis, Marri Laxman Reddy Institute of Pharmacy, Dundigal, Hyderabad, Telangana, India-500043*

Received: 4th Nov, 2024; Revised: 23rd Dec, 2024; Accepted: 19th Feb, 2025; Available Online: 25th Mar, 2025

ABSTRACT

Background: The suggested approach is appropriate for the quantitative measurement of Remdesivir and Griseofulvin in a variety of pharmaceutical dosage forms, according to experimental findings. The technique offers excellent repeatability, linearity, and sensitivity. Remdesivir and Griseofulvin were estimated using RP-HPLC.

Objective: The objective was to accomplish method development and validation of Remdesivir and Griseofulvin.

Materials and Methods: The mobile phase was adjusted and consisted of acetonitrile and phosphate buffer mixed in a 70:30% v/v ratio. 4.6 was the pH of the phosphate buffer. An X Terra Symmetry C18 (4.6 x 250mm, 5µm) column is used as the stationary phase. For the detection, a UV detector tuned to 221 nm was employed. Chromatography of the solutions was performed at a constant flow rate of 1.0 ml/min. Many trials have been carried out to obtain an optimized chromatogram.

Results: Remdesivir and Griseofulvin were reported to have linearity ranges of 25-125 µg/ml. There was no increase in the linear regression coefficient above 0.999. The accuracy and precision of the procedure are indicated by the percentage RSD readings being less than 2%. The percentage recovery for Griseofulvin and Remdesivir ranges from 97 to 100%. It was discovered that LOD and LOQ were inside the range.

Conclusion: The suggested technique for figuring out how much Remdesivir and Griseofulvin are in a formulation is exact, easy to use, and accurate. A high recovery rate indicates that the formulation's excipients are not interfering with the process. Therefore, the technique may be helpful for routinely checking the quality of these medications.

Key words: Symmetry C18, Remdesivir, Griseofulvin, RP-HPLC.

How to cite this article: Rakam Gopi Krishna, Kadagoni Pravalika, Ramesh Konda, V A N V Harita, G. Haritha. Analytical Method Development and Validation of Remdesivir and Griseofulvin in API and its Dosage Form by RP-HPLC. International Journal of Drug Delivery Technology. 2025;15(1):139-45. doi: 10.25258/ijddt.15.1.19

Source of support: Nil

Conflict of interest: None

INTRODUCTION

According to both the Indian and British Pharmacopoeias, Remdesivir is an approved medication.[1] A moderate spectrum bacteriolytic β-lactam antibiotic, Remdesivir is used to treat bacterial infections brought on by susceptible microbes. Because it is more readily absorbed when taken orally, it is typically the preferred medication in the class. By preventing the creation of bacterial cell walls, Remdesivir works. It is somewhat soluble in ethanol, soluble in water, methanol, and somewhat insoluble in toluene. Griseofulvin belongs to the group of medicines called antifungals. It is used to treat fungus infections of the body, feet, groin and thighs, scalp, skin, fingernails, and toenails.[2] According to a review of the literature, there aren't many spectrophotometric and analytical techniques available for quantitatively estimating Remdesivir in pharmaceutical formulations and bulk drugs. Therefore, an effort has been made to create novel HPLC techniques that can accurately, precisely, linearly, and reproducibly estimate it in pharmaceutical formulations and bulk.[3] Ions or molecules dispersed in a solvent can be separated using the analytical chromatographic method known as high performance liquid chromatography. The various solutes interact with the other phase to varying degrees whenever the sample solution comes into contact with a second solid or liquid phase because of variations in size or adsorption ion exchange partitioning.[4] A liquid mobile phase elutes through a stationary phase in a column in liquid chromatography, a separation process based on the difference in component distribution between two non-miscible phases. The three types of HPLC that are most frequently employed are based on ion exchange, adsorption, and partition mechanisms, Amoxycillin, another name for Remdesivir, is an antibiotic that can be used to treat a variety of bacterial infections.[5] In addition to treating skin infections, urinary tract infections, and pneumonia, it is the 1st line medication for infections of ear. Injecting the subject is less usual than taking it orally. When used with clavulanic acid, it may raise the risk of yeast infections and cause common side effects like redness and nausea. People with penicillin allergies shouldn't use it. Although the dosage may need to be lowered in patients with kidney issues, it is

**Author for Correspondence: gopirakam@gmail.com*

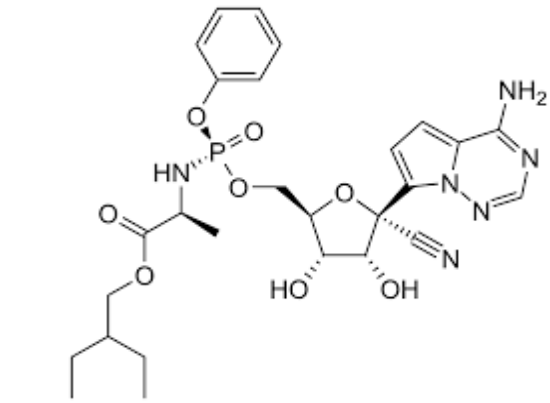

Figure 1: Structure of Remdesivir

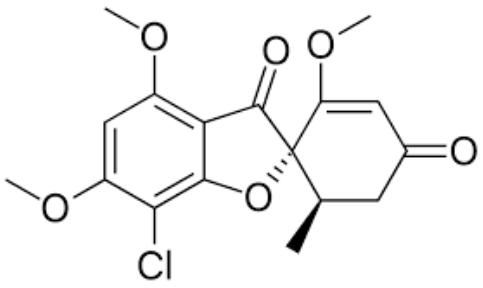

Figure 2: Structure of Griseofulvin

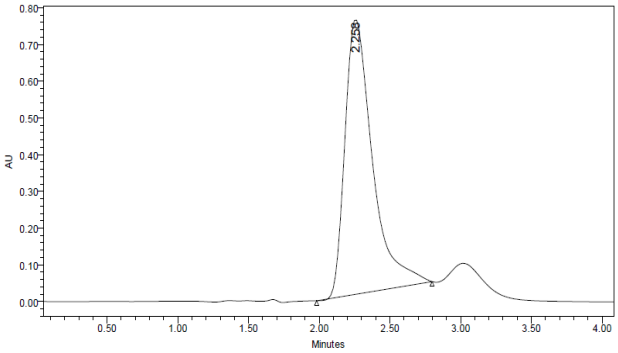

Figure 3: Trial chromatogram-1

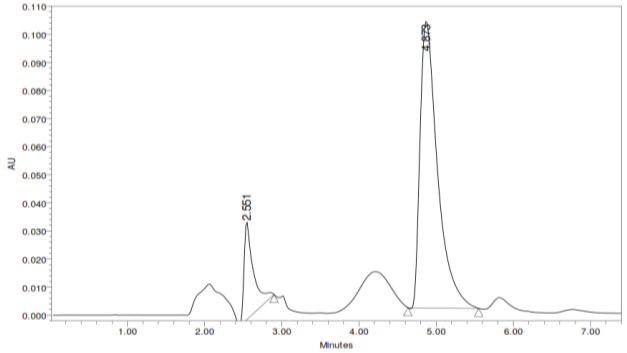

Figure 4: Trial chromatogram-2

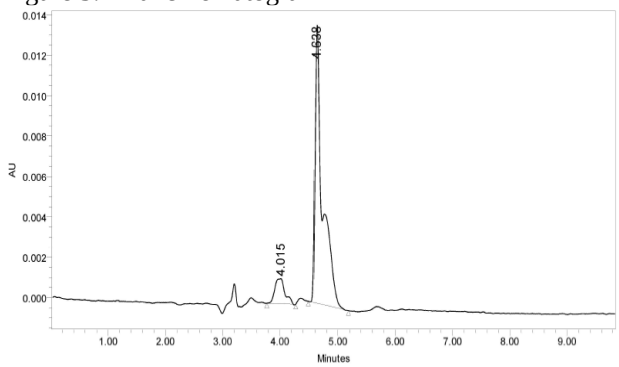

Figure 5: Trial chromatogram-3

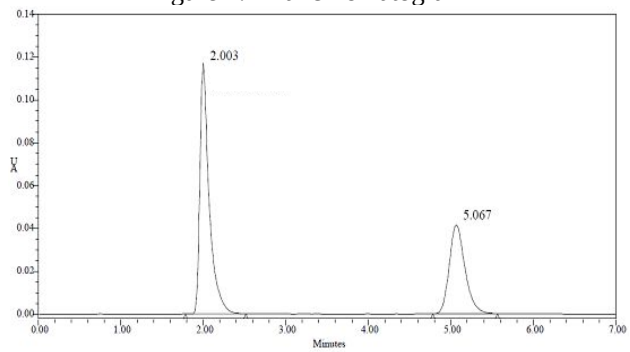

Figure 6: Optimized Chromatogram

Table 1: System suitability parameters for Remdesivir and Griseofulvin

S. No	Name	Retention time(min)	Area (µV sec)	Height (µV)	USP resolution	USP tailing	USP plate count
1	Remdesivir	2.003	920101	116666		1.6	2711.8
2	Griseofulvin	5.067	552058	41531	11.0	1.3	3428.2

still usable. It seems to be safe to use during pregnancy and lactation. The current study's objectives are to create a novel approach and validate the tablet dosage forms of the medications Remdesivir and Griseofulvin.

Drug Profile

Remdesivir

The formal condensation procedure yields the carboxylic ester remdesivir. a broad-spectrum antiviral prodrug that exhibits strong antiviral activity *in vitro* in opposition against several RNA viruses, such as the Ebola virus, MERS-CoV, and SARS-CoV. Phase III clinical studies are presently being conducted to treat COVID-19 in adults. It functions as a prodrug, an anticoronaviral agent, and an antiviral medication. It is an aromatic amine, a carboxylic ester, a pyrrolotriazine, a phosphoramidate ester, a nitrile, and a C-nucleoside. Acute respiratory syndrome that is severe. The cause of coronavirus disease 2019, a respiratory illness it can develop into viral pneumonia.

Mechanism

Remdesivir's method of action suggests broad antiviral activity, and it has shown invitro activity against a variety of virus and microbe species to far. After remdesivir's first demonstration of action against the coronaviridae family in 2017, there was a lot of interest in remdesivir as a potential COVID-19 treatment. In multiple COVID-19 clinical trials, Remdesivir has been investigated and has been verified as an optional chain terminator of SARS-CoV-2's RdRp. The FDA first granted Remdesivir an Emergency Use

Table.2: Showing Precision observation of Remdesivir

S. No	Sample area	Standard area	Percentage purity
1	981234	972121	100.32
2	989645	972999	100.25
3	982534	976121	100.68
4	984519	979012	100.12
5	993965	981521	100.89
Average			100.45
%RSD			0.30

Table.3: Showing Precision observation of Griseofulvin

S. No	Sample area	Standard area	Percentage purity
1	593569	579874	100.25
2	599563	582546	100.57
3	598741	574563	100.89
4	591235	585826	100.55
5	593214	583658	100.32
Average			100.516
%RSD			0.51

Authorization on May 1st, 2020, and on October 22, 2020, the FDA gave it full approval to treat COVID-19. Gilead Sciences Inc. now markets Remdesivir under the trademark name VEKLURY. On July 3, 2020, the European Commission also authorized Remdesivir.

Griseofulvin

One mycotoxin produced by Penicillium species is Griseofulvin. It has been in use for more than 40 years and was the first oral medication to treat dermatophytoses. *In vitro*, Griseofulvin exhibits fungistatic action against a variety of Macrospore Epidermophyton and Trichophyton species. Both bacteria and other fungal genera are unaffected. Griseofulvin has a higher affinity for sick tissue after oral dosing and is deposited in the keratin precursor cells. The new keratin is firmly attached to the medication, making it extremely resistant to fungal infestations. The keratin-Griseofulvin combination changes fungal mitosis by binding to fungal microtubules (tubulin) once it reaches the skin site of action.

Mechanism:

Although griseofulvin is fungistatic, it is unclear exactly how it prevents dermatophyte growth. It is believed to prevent nuclear acid production and fungal cell mitosis. Additionally, it attaches itself to alpha and beta tubulin and disrupts the activity of spindle and cytoplasmic microtubules. After attaching itself to keratin in human cells, it attaches itself to fungal microtubes at the site of action, changing the fungal mitotic process.

MATERIALS AND METHODS

Chemicals and Reagents

Remdesivir & Griseofulvin was supplied by Concept Pharmaceuticals Ltd. (Aurangabad, India). the formulation of commercially available capsules. A quantitative evaluation was conducted using Flumox® Capsules. The potassium dihydrogen orthophosphate utilized was analytical grade. The water, methanol, and HPLC-grade acetonitrile were purchased from Merck Chemicals Ltd. in Mumbai. HPLC, double-distilled RO water was used to make all of the solutions.

Chromatographic conditions

In light of the analytes' solubility, polarity, and chemical differences, the Agilent C18 column (4.6 x 250 mm, 5µm) and a mobile phase comprising a 70:30% v/v mixture of phosphate buffer and ACN were selected. The flow rate (1 ml/min) was maintained constant. Eluted compounds were visible at a wavelength of 221 nm while the temperature was kept at 30°C for column. 20µl was the sample's injection volume. ACN (70:30%v/v) phosphate buffer has been selected as the mobile phase.

Preparation of diluents

The drug solubility was taken into consideration while choosing the diluent for analysis. Diluent employed is Mobile Phase.

Preparation of Buffer

0.01N KH_2PO_4 Buffer

The 0.01N KH_2PO_4 Buffer consists of precisely weighing 1.36g of potassium dihydrogen orthophosphate in a1Lvolumetric flask, adding milli-Q water about 900ml,

Table.4: Accuracy table of Remdesivir and Griseofulvin

Sample conc.	Sample set no	Sample area		Assay		% Recovery	
		Remdesivir	Griseofulvin	Remdesivir	Griseofulvin	Remdesivir	Griseofulvin
50%	1	460064	276931	24.9	25.0	99.1	98.9
	2	460124	276694	24.6	24.9	99.3	99.2
	3	460216	276891	24.8	24.9	98.9	98.8
	Average Recovery					99.1%	98.9%
100%	1	921247	565214	48.8	49.8	98.9	99.9
	2	938547	555123	48.7	49.4	98.2	98.7
	3	931579	558963	48.6	49.2	97.8	97.5
	Average recovery					98.6%	98.7%
150%	1	1365401	819875	75.3	74.1	99.9	99.6
	2	1379854	815634	76.9	75.2	99.7	99.5
	3	1378123	819875	77.1	75.3	99.1	98.9
	Average recovery					99.5%	99.3%

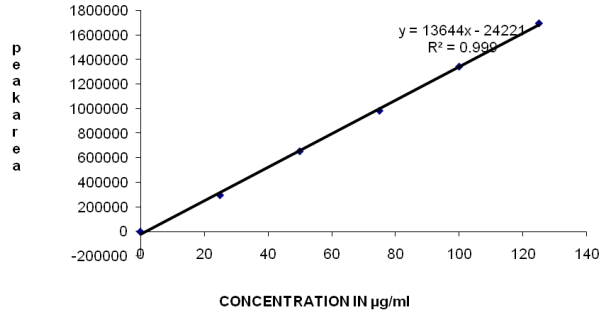

Figure. 7 Calibration graph for Remdesivir

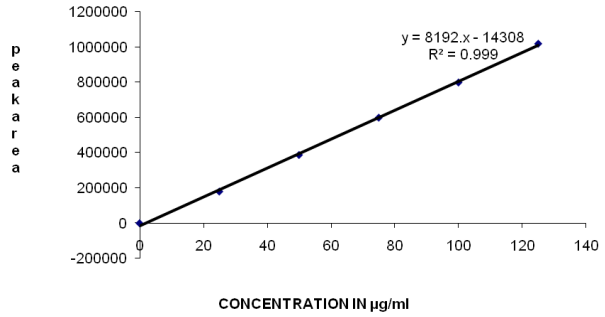

Figure.8 Calibration graph for Griseofulvin

Table.5: Sensitivity table of Remdesivir and Griseofulvin

Molecule	LOD	LOQ
Remdesivir	0.08	0.29
Griseofulvin	1.71	5.15

degassing to sonicate, and then volume was made with water and dilute formic acid to bring the pH down to 5.4.

Preparation of mobile phase

For five minutes, a mixture of 300 ml of 70% phosphate buffer pH 4.0 and 700 mL of 30% ACN are degassed in an ultrasonic water bath. Next, under vacuum filtration, this solution is passed through a 0.45 µ filter.

Preparation of the individual Remdesivir and Griseofulvin standard preparation

After precisely weighing 10 mg of the Remdesivir and Griseofulvin working standard, it was placed into a cleaned, dry volumetric flask and up to 2.1 ml of DMF was poured to it. After being fully dissolved by sonication, the volume is adjusted with the diluent. (A stock solution). Furthermore, the aforementioned stock solution (10.1 ml) was pipetted into a 100 ml volumetric flask and diluted with diluent until the appropriate level was achieved.

Preparation of Sample Solution:(Tablet)

A mortar and pestle is used to crush ten carefully weighed tablets in a 10 mL clean, dry volumetric flask later, it was weighed equal to 10 mg of Remdesivir and Griseofulvin sample. Approximately 7.1 mL of diluents are then poured, sonicated to completely liquify the tablets, and the composition is adjusted using the same solvent. (A stock solution) A 10-milliliter volumetric flask was pipetted with three milliliters of the aforesaid stock solution, which was then diluted with diluent to the appropriate level.

Method development

Numerous experiments using different stationary phases, flow rates, and mobile phases have been conducted. The stability factor and theoretical plates were examined, and then different chromatographic settings were selected. The mobile phase composition is Phosphate buffer: ACN (70:30 %v/v) and column [Column: Agilent C18 (4.6 x 250mm, 5µm] with a mobile phase encompassing a mixture of Phosphate buffer: ACN (70:30 %v/v) has been selected for mobile phase**.** A constant flow rate of 1 ml/min was maintained. At 221 nm wavelength, eluted chemicals were seen while at 30°C, the column temperature was kept constant. The injection volume of the sample was 20µl. [6]

Method validation

The method's robustness, ruggedness, accuracy, precision, and linearity were assessed in compliance with ICH requirements.[7]

System suitability parameters

Six injections of standard solutions containing 5 ppm of Remdesivir and 100 ppm of Griseofulvin were used to measure variables such peak tailing, resolution, and USP plate count. This process allowed for the further determination of all the system suitability parameters as well.

It is advised that the 6 injection of standard produce' percentage RSD do not go more than 2%.

Linearity

2.5 mg of Remdesivir and 2.5 mg of Griseofulvin were precisely weighed before being put to volumetric flask. Later flask was sonicated for 10 minutes succeeding to accumulation of 3/4 Th of the diluents. Following the addition of diluents, the flask was labeled "Standard stock solution." 1. The method's linearity was proven over the 10-50 µg/ml concentration range. From the stock solution aliquots of diverse compositions were put transferred to a 50 ml volumetric flask and diluted with mobile phase to the brim to attain a diverse concentration of 25, 50, 75, 100, 125, 150 ppm respectively. As per the test protocol, after being injected, the solutions into HPLC apparatus. For concentration v/s peak area, a calibration curve was created.

Acceptance criteria

A Correlation coefficient of 0.9990 or above is required. % RSD of peak areas should not exceed 2.0 % for solutions 1, 2, 3, 4, 5, 6, 7.

Precision/ System precision (Repeatability)

From the sample stock solution, a sample solution of 25 ppm is prepared and it was injected for six times to the HPLC instrument according to procedure.

Acceptance criteria

The range for each Remdesivir and Griseofulvin tablet assay should be between 98% and 102%.

The relative standard deviation of current assay shouldn't be higher than 2.0%.

Method precision

From sample and stock solution, six replicates of solutions of 25 ppm were organized and injected to the HPLC instrument according to procedure**.**

Acceptance criteria

Table.6: Griseofulvin and Remdesivir robustness data.

S.no	Condition	%RSD of Remdesivir	%RSD of Griseofulvin
1	Flow Minus	1.1	1
2	Flow Plus	1.2	1.4
3	Mobile phase Minus	0.75	0.68
4	Mobile phase Plus	0.59	0.61
5	Temperature Minus	1	0.9
6	Temperature Plus	1.2	0.7

The range for each Remdesivir and Griseofulvin tablet assay should be between 98% and 102%.

The RSD of current assay shouldn't be higher than 2.0%.

Accuracy

A series of solutions were prepared in triplicate (6 preparations for 50 and 150% level) by adding 50-150 spiking units of the medication substances Remdesivir and Griseofulvin to a placebo of test concentration and analyzed as per specification level triplicate injections for 50%, 100% and 150%. Individual % recovery, mean % recovery, % RSD and linearity were evaluated at each level.[8]

Limit of detection

The standard deviation of the intercepts was evaluated for each of the three runs.

The LOD was calculated using the formula below.

$LOD = 3.3\ \sigma/S$.

The standard deviation is denoted by σ of the calibration curve intercept.

S is the calibration curves' average slope.

The calibration curve of the analyte can be used to determine the slope S.

Limit of quantification

Three runs of calibration curve were performed, & each time standard deviation of intercepts were evaluated.

Following formula used to get the LOQ:

$LOQ = 10\ \sigma /\ S$

Robustness

The impact of slight variations in the buffer's pH (± 0.2 units), the column temperature (± 5%), the mobile phase's organic content (± 2%) and the flow rate (± 5%) on robustness was tested.10

Degradation studies

Acid Degradation Studies

30 minutes at 600 degrees Celsius were spent refluxing 1 milliliter of stock solution and 1 milliliter of 2N hydrochloric acid containing Remdesivir and Griseofulvin. Following the addition of 10 µl solutions to the system, chromatograms were produced to evaluate the sample's stability and the subsequent mixture was diluted to produce solutions of 5µg/ml & 100µg/ml. [9]

Alkali Degradation Studies

A milliliter of 2N sodium hydroxide was mixed with one milliliter of the stock mixture comprising Remdesivir and Griseofulvin. The combination was subjected to reflux for thirty minutes at 600º C. Later,10 µl of the sample was added in to the system and the resulting Distilled solution to yield 100 µg/ml & 10 µg/ml, Later, chromatograms were obtained.

Oxidation

Separate milliliters of the stock solutions of Remdesivir and Griseofulvin were added with one milliliter of 21% H_2O_2. For thirty minutes, the solutions were kept at 600 degrees Celsius. To estimate the steadiness of sample for the analysis of HPLC, 10 µl of the subsequent solution injected into the system later, it had been diluted to produce solutions containing 5 µg and 100 µg/ml. Chromatograms were then recorded.

Dry Heat Degradation Studies

To investigate dry heat deterioration, a normal medicine solution was heated to 105°C in an oven for six hours. For HPLC investigation, then resulting solution was dilute to 5µg/ml&100µg/ml composition &10µl are injected in to the system & later chromatograms are documented to evaluate stability.

Photo Stability studies

Durability of the medicine against light was investigated through subjecting 50µg/ml & 1000µg/ml solutions to radiation of UV and placing the beaker in UV cabinet for seven days. After being diluted to create 5µg/ml and 100µg/ml solutions, The system received an injection of 10 µl of the resulting solution to evaluate sample stability for the HPLC analysis. After then, chromatograms were recorded.

Neutral Degradation Studies

The compounds were refluxed in water for six hours at 60 degrees Celsius to assess it. To test the sample's stability, 10 µl of the resultant solution is put to the system and diluted with 5 µg/ml & 100 µg/ml for the HPLC examination. Finally, chromatograms were recorded.

Assay

Prior to injection of drug solutions, for at least half an hour, the column was equilibrated, and the mobile phase was moving through the system at a flow rate of 1.0 milliliters per minute. After that, 20 µl of the standard was made, and sample solutions were injected for six times and 2 times respectively. The chromatograms were recorded to measure peak responses in Remdesivir and Griseofulvin standard and sample solutions.

Table.7: Data showing forced degradation studies of Remdesivir and Griseofulvin.

Type of degradation	Remdesivir			Griseofulvin		
	Area	%Recovered	% Degraded	Area	%Recovered	% Degraded
Acid	60987	84.66	15.34	1186676	94.34	5.66
Base	64354	98.24	1.76	1256767	99.90	0.10
Peroxide	61787	94.34	5.66	1186566	94.33	5.67
Thermal	64342	98.13	1.87	1247677	99.16	0.84
Uv	64786	98.92	1.08	1237677	98.37	1.63
Water	65078	99.36	0.64	1237565	98.35	1.65

RESULTS AND DISCUSSION

In the contemporary study, the determination of Remdesivir and Griseofulvin are shown. A variability of buffer and solvent ratios was assessed to determine the proper mobile phase composition. Many studies were directed to improve the chromatographic settings and achieve augmented chromatographic system efficiency. These comprised changing the stationary phase selection, pH, concentration of the mobile phase, and more. In trail-1chromatogram, the sharp peak was not produced (Fig.3). Thus, additional testing is done. In trial-2, both peaks were eluted but exhibited base line disturbances with no tailing factor for one drug (Fig.4). Thus, additional testing is done. Both peaks were eluted in trial 3, however they did so within the range of the void volume (Fig.5). Thus, additional testing is done. Remdesivir and Griseofulvin eluted with good peak shape and symmetry in the trial-4 chromatogram. The resolution, theoretical plate count, resolution, and tailing factor of both peaks are good. Six minutes was the total playtime allotted to each validation parameter. With good repeatability, the component was eluted at a reduced retention time. Hence this method was optimized (Fig.6).

Observation

With an upright resolution, Remdesivir and Griseofulvin were eluted at 2.216 and 2.650 minutes, respectively. This approach was optimized and validated as a result of the extremely good plate count and tailing factor.

System suitability

The results of the system suitability investigation were characterized with the use of several standard chromatographic trials. To calculate the tailing factor, USP plate count, and retention time, six replicate injections for Remdesivir and Griseofulvin were employed. The results were shown in Table 1.

Linearity

For six concentrations, the optimized method's linearity was established. In this, six identical injections of Remdesivir (25-150 µg/ml) and Griseofulvin were made. The linearity equations for Remdesivir and Griseofulvin were y = 13644x - 24221 and y = 8192.xx - 14308, correspondingly, based on the average areas previously reported. A correlation value of 0.999 was discovered for the two drugs. The results of linearity were displayed in Figs. 7 and 8.

Precision

System precision (Repeatability)

6 injections were prepared from a single volumetric flask comprising the standard working solution, and also areas acquired are earlier defined. The standard deviation, average area and % RSD were calculated for two medicines. The percentage RSD for Remdesivir and Griseofulvin was determined as 0.30% and 0.51%, correspondingly. This solution is successful in passing the system precision since the precision limit was less than "2". Every parameter was within the allowed range. Table.2 & 3 presented the Precision results.

Accuracy

Three distinct levels of accuracy were created in samples using the typical addition process. Three shots are given for each accuracy level and mean percentage. Sample solutions were spiked at wildly disparate concentrations (50, 100, and 150 percent), and the recovery was also computed. The retrieval rates for Remdesivir and Griseofulvin were found. At each level, the recovery percentage should range from 98 to 100%. The recovery outcomes at five hundredth, 100%, and one hundred and fifty area units inside the limits. Results were revealed in Table. 3 & 4. Robustness is determined by making minor or intended changes to the optimum method.[10]

Detection and Quantification limits

The signal to noise ratio was used to calculate both. Results showed that the quantification limit was 0.29µg/ml, LOD was 0.08 for Remdesivir and for Griseofulvin LOD & LOQ was 1.71 & 5.15 correspondingly which was within the acceptance range. The results were shown in Table 5.

Entire system suitability parameters accepted with minimal to no impact. %RSD stayed below upper bound.

Robustness data was indicated in Table.6

Forced degradation studies

Studies on degradation were carried out using degraded samples and formulation. The percentage of the medicine that degraded in response to acid, alkali, peroxide, heat, UV light and water was 6.89, 1.76, 5.66, 1.87, 1.08, and 0.64 for Remdesivir and 5.66, 0.10, 5.67, 0.84, 1.63, and 1.65 for Griseofulvin, all of which were within the acceptable range. In Table.7 mentioned degradation data

CONCLUSION

For the simultaneous valuation of Remdesivir and Griseofulvin in collective capsule dosage form, API, the proposed method was found to be simple, fast, accurate, and precise. It can also be used for routine evaluation of Remdesivir and Griseofulvin dosage form based on the assay results and validation parameters.

Acknowledgements

The management of Marri Laxman Reddy Institute of Pharmacy, Dundigal, Telangana, India, is appreciated by the authors for providing the resources needed to complete the research.

REFERENCES

1 Manzoor A. Development and Validation of Remdesivir by RP-HPLC Method in Bulk drug and Pharmaceutical dosage forms. International Journal of Chem Tech Research. 2011;3(3);1037-1041.

2 Dadinaboyina SB, Yerra NV, Adimoolam BM, Parsa S and Bathini NB. Identification and characterization of degradation products of Remdesivir using liquid chromatography/mass spectrometry. New Journal of Chemistry 2021; 45(16): 7217-7224.

3 Hoang Vu. Comparative Study of RP-HPLC and UV Spectrophotometric Techniques for the Simultaneous Determination of Remdesivir and Griseofulvin in Capsules. Journal of Young Pharmacists. 2010; 2(2): 190-195. https://doi.org/10.3390/separations8120243

4 Nidal BA. Validated Stability-Indicating HPLC Method for Simultaneous Determination of Remdesivir and Griseofulvin Combination in an Injectable Suspension. 2017;85(1):1-6.

5 Pasupuleti RR, Tsai PC, Ponnusamy VK, Pugazhendhi A. Rapid determination of Remdesivir (SARS-CoV-2 drug) in human plasma for therapeutic drug monitoring in COVID-19-Patients.ProcessBiochem.2021;10(2):150-156.doi: 10.1016/j.procbio.2020.12.014.
6 Rakam Gopi Krishna, M. Srinivasa Murthy, V. Kavya. Method development and validation of RP-HPLC method for the determination of sumatriptan in bulk and pharmaceutical dosage form. Research Journal of Pharmacy and Technology. 2021; 14(11):5856-2. doi: 10.52711/0974-360X.2021.01019
7 ICH- Harmonised Tripartity Guideline, Validation of Analytical Procedures: Text and Methodology Q2 (R1). IFPMA: Geneva, 2005.
8 Rakam GK, Mallik A, Sucharitha Ch. Method Development and Validation of RP-HPLC Method for Estimation of Ondansetron and Pantoprazole in their Tablet Dosage Form. Indian Journal of Pharmaceutical Sciences. 2022; 84(2): 483-492. DOI: 10.36468/pharmaceutical-sciences.942
9 Gopi Krishna R, Manjeera K, Lalitha R. A validated spectrophotometric method for the estimation of Ezetimibe in bulk and tablet dosage form. Indo American Journal of Pharmaceutical Research. 2013; 4(4): 2231-6876. DOI: 10.1044/1980-iajpr.472.
10 Deshmukh SB, Wagh PA, Yadav SS, Mane MB. Stability-Indicating HPLC Method Development and Validation for the Simultaneous Determination of Vildagliptin and Dapagliflozin in Pharmaceutical Dosage Form. International Journal of Drug Delivery Technology. 2024;14(3):1600-1603.