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Development, Validation and Forced Degradation Study of Maribavir in its Pharmaceutical Dosage Form Using RP-HPLC

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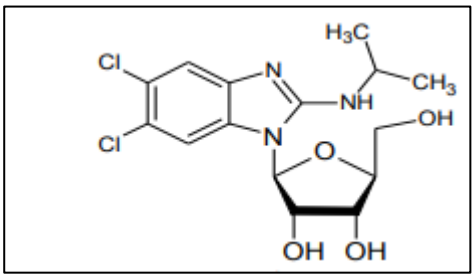
ABSTRACT:

The present research was aimed to develop and validate a reverse phase high performance liquid chromatographic (RP-HPLC) method for the quantification of Maribavir. Agilent Eclipse C_{18} column (250 x 4.6 mm, 5.0 µm). Borwin-PD software (version1.50) HPLC pump-Model PU2080 Plus Rheodyne sample injection port–20µl loop. ACN: Methanol (60:40 v/v).The flow rate is 0.8 ml/min and the detection was carried out at 239 nm. The chromatographic condition, the peak retention times of Maribavir were found to be 6.478 ± 0.376 min respectively. The method was validated as per ICH Q2 R1 guidelines. The calibration curve was found to be linear in the concentration range of 2-12 µg/ml. The limit of detection and quantification was found to be 0.213 µg/mL and 0.644 µg/mL for Maribavir respectively. Maribavir was determined using a new sensitive, simple reverse-phase high-performance liquid chromatography [RP-HPLC] approach that was developed and validated. The proposed developed RP-HPLC method was validated statistically and the values were found to be within the acceptable limits. The proposed approach can be used to routinely determine Maribavir.

Keywords: RP-HPLC, Maribavir, ICH Q2 R1, Method validation

1 INTRODUCTION

Maribavir is a cytomegalovirus (CMV) pUL97 kinase inhibitor and antiviral class medical drug prescribed for the treatment of treat post-transplant cytomegalovirus1 . It is indicated for the treatment of paediatric patients (weighing >35kg and at least 12 years old) and adult with post-transplant CMV infection which is refractory to standard treatment with foscarnet, cidofovir, ganciclovir and valganciclovir. Maribavir blocks the virus replication by inhibiting the activity of human CMV pUL97 enzyme. Fatigue, diarrhea, nausea, vomiting and taste disturbance are common side effects of Maribavir2.



Structure of Maribavir

Maribavir is a benzimidazole riboside antiviral agent that competitively inhibits the protein kinase activity of human CMV enzyme pUL97, which results in inhibition of the phosphorylation of proteins. [3-4] In dose-ranging studies, no exposure-response relationship was observed for viral load or probability of achieving unquantifiable plasma CMV DNA. Maribavir has also been shown to inhibit Epstein-Barr virus replication. [5-6]

Maribavir is a weak inhibitor of CYP3A4 and an inhibitor of P-gp and BCRP. Coadministration of maribavir with drugs that are sensitive substrates of CYP3A, P-gp, and BCRP may result in a clinically relevant increase in plasma concentrations of these substrates.[7-8]

2.Materials and Method:

2.1 Chemical and Reagents:

Samples of Maribavir were supplied as the Takeda Pharmaceuticals U.S.A., Inc**.** Acetonitrile, Methanol (HPLC Grade), HPLC grade water, all the chemicals that is Methanol and Acetonitrile were brought from Merck Laboratories PVT. LTD., Mumbai.

2.2 Instrumentation:

Chromatography was carried out using a Borwin-PD software (version1.50) HPLC pump-Model PU2080 plus, Shimadzu (modelATX-224R) Electronic weighing balance, Sonicator–Pharma solutions for laboratory.

2.3 Preparation of solutions Standard stock solution:

An accurately weighed 10 mg of Maribavir was transferred to 10 ml volumetric flask and the volume was made up to 10 ml with acetonitrile, to get standard stock solution of Maribavir (1000 µg/ml). From the standard stock solution, working standard solution was prepared using mobile phase as final diluent.

2.4 Selection of analytical wavelength:

A solution of 10 µg/ml was prepared from standard stock solution of Maribavir (1000 µg/ml) and scanned over 200- 400 nm in UV–Spectrophotometer. The maximum absorbance peak was shown at 239 nm. Hence it was selected as analytical wavelength; The UV spectrum is given in Figure 1.

2.5 Mobile phase optimization:

To achieve optimum chromatographic condition various mobile phases were checked. Methanol: water (75: 25 v/v) system was initially tried but peak shape was not proper. Methanol was replaced by Acetonitrile with ACN: Water (60:40v/v) as mobile phase but did not get a considerable number of theoretical plates being peak shape was broad. ACN has been chosen as organic modifier here. Further water proportion was reduced with ACN: Water (80:20 v/v) was tried has obtained considerable theoretical plates and appropriate peak shape with appropriate system suitability parameters.

2.6 Assay:

Assay of Maribavir was done on synthetic mixture due to unavailability of its marketed preparation in Indian market. 20 mg of Maribavir was mixed with equal amounts of lactose monohydrate and cellulose microcrystalline to make 60 mg of blend in mortar Pestle. The contents were properly mixed. Spike blend (equivalent to 10 mg) of Maribavir was accurately weighed and transferred into a 10 ml volumetric flask and volume made up with acetonitrile as mentioned under section preparation of stock solution (1000 µg/ml). The volumetric flask was sonicated for 10 min to enable complete dissolution of Maribavir and filtered. The further dilution was made with acetonitrile to get 100 µg/ml solutions. The solution was further diluted with mobile phase to yield a concentration of 4 µg/ml and then it is injected. The procedure was repeated for six times.

2.7 METHODVALIDATION:

Validation of analytical method involves linearity and range, precision, specificity, assay, accuracy, limit of detection (LOD) and limit of Quantitation (LOQ).It was validated according to ICH Q2 (R1) guideline.

2.7.1 Linearity and Range:

Linearity is the ability of the analytical method to obtain results that are directly proportional to concentration of the analyte in the sample. From the standard stock solution (1000 µg/ml) of Maribavir, solution was prepared containing 100 µg/ml in Acetonitrile. This solution was further used to prepare range of solution containing six different concentrations. The linearity (relationship between peak area and concentration) was determined by analyzing six solutions over the concentration range of 2-12 µg/ml, the equation of calibration curve was found to be y = 129090x + 113861. Following that, the values were plotted as concentration versus peak area, and the calibration curve is displayed in Figure 6. The result of linearity displayed in Table 4, and the overlay of the linearity data is shown in Figure 5.

2.7.2 Precision:

The precision of the method was demonstrated by intra-day and inter-day variation studies. In the Intra-day studies, 3 replicates of 3 different concentrations were analyzed in a day and percentage RSD was calculated. For the inter day variation studies, 3 different concentrations were analyzed on 3 consecutive days and percentage RSD was calculated. Table 5 and 6 show the findings for intraday precision and interday precision, respectively.

2.7.3 Accuracy:

To check accuracy of the method, recovery studies were carried by spiking the standard drug to the sample solution, at three different levels around 50, 100 and 150 %.Basic concentration of sample solution chosen was 4 µg/ml. % recovery was determined from linearity equation. Table no 7.

2.7.4 Limit of Detection (LOD) and Limit of Quantitation (LOQ):

The detection limit and Quantitation limit of drugs were calculated from calibration curves. The calculation is based on the standard deviation of y intercept and the slope of the calibration curves. The following equations were used to calculate LOD and LOQ. The results obtained are summarize in Table 8.

$$\mathbf{LOD=3.3 \times \sigma/S}$$

$$\mathbf{LOQ=10\times\sigma/S}$$

Where, σ = the standard deviation of y intercept. S = slope of the calibration curve

2.7.5 Robustness:

Robustness of the method was checked by carrying out the analysis under conditions during which mobile phase composition (± 2 ml Composition), detection wavelength (± 1 nm), flow rate (± 0.05 ml/min) were changed and the effect on the area were noted. Robustness of the method checked after deliberate alterations of the analytical parameters showed that areas of peaks of interest remained unaffected by small changes of the operational parameters indicating that the method is robust. Table no 9.

2.8 Forced Degradation Studies:

The effect of different environmental factors on drug stability and quality must be checked. Thus, the drug was subjected to various stress conditions for varying periods of time, using various strengths of reagents. Conditions were tried to optimize to achieve recovery of 70- 90%. The Maribavir standard was exposed to acid and alkaline hydrolysis, oxidation, photolytic and thermal degradation condition. All studies were done at 100 µg/ml concentration of sample. Summary of forced degradation shown in Table 10.

3. Result and Discussion:

The maximum absorbance was shown at 239 nm. Hence it was selected as analytical wavelength; The UV spectrum is given in Figure 2.

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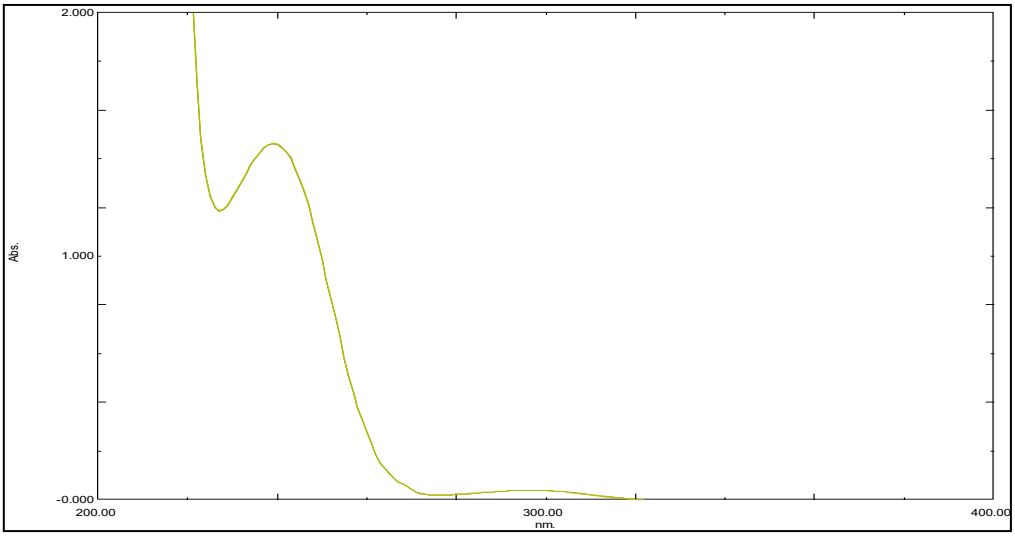
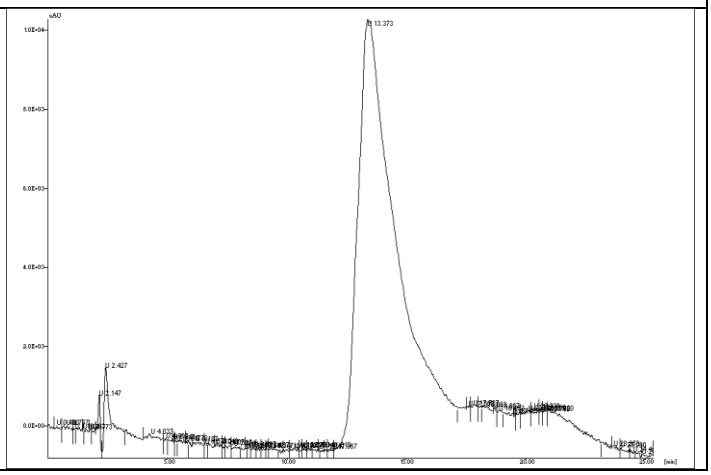


Figure 2: UV spectrum of Maribavir (10 µg/ml) For HPLC

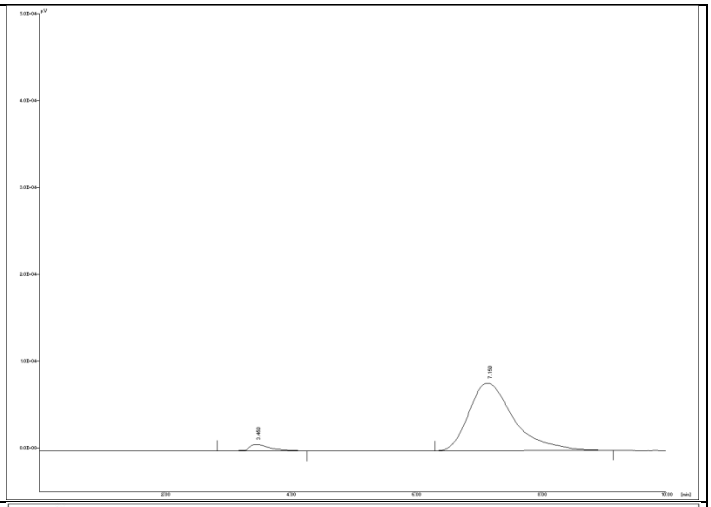
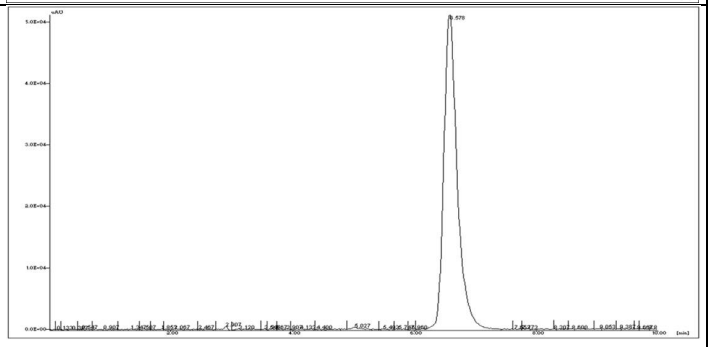
3.1 Mobile phase optimization:

Agilent Eclipse C_{18} column (250 x 4.6 mm, 5.0 µm). Borwin-PD software (version1.50) HPLC pump-Model PU2080 Plus Rheodyne sample injection port–20µl loop. ACN: Methanol (60:40 v/v)

Table 1: Trials of mobile phase for Maribavir

Sr. No.	Column and M.P.	Observation	Chromatogram(239nm)
1.	MeOH: Water (75: 25 v/v)	Peak was not good shape (Tailing, High Retention Time 13.373 min)	

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 7, July 2025 ijppr.humanjournals.com ISSN: 2349-7203

2.	ACN:Water (60:40v/v)	Broad Peakobserved (RetentionTime 7.150 min)	
3.	ACN:Water (80:20v/v)	R.T 6.478 min Good shape of peak	

Final Method: Agilent Eclipse C18 column (250 x 4.6 mm, 5.0 µm). Borwin-PD software (version1.50) HPLC pump-Model PU2080 Plus Rheodyne sample injection port–20µl loop.ACN: Methanol (60:40 v/v)

Table 2: System suitability parameters of Maribavir.

Sr.No.	Parameter	Obtained values
1	Column	Grace smart RP 18 Column (150 × 4.6 mm, 3.5 µ)
2	Mobile Phase	Acetonitrile: Water (80: 20v/v)
3	Flow rate	0.8 ml/min
4	Detection wavelength	239 nm
5	RT	6.478 ± 0.376

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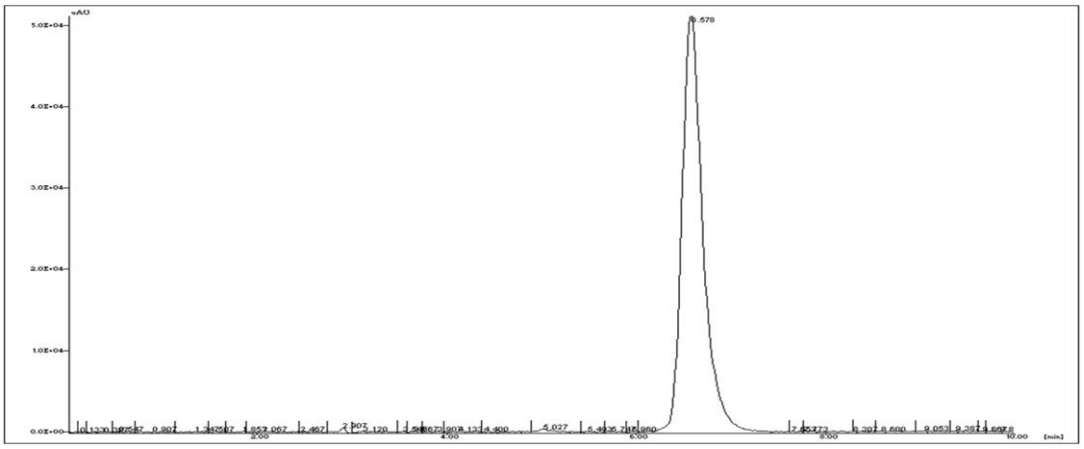

Figure 3: Chromatogram of Standard Maribavir (10µg/ml)

3.2 Analysis of tablet formulation:

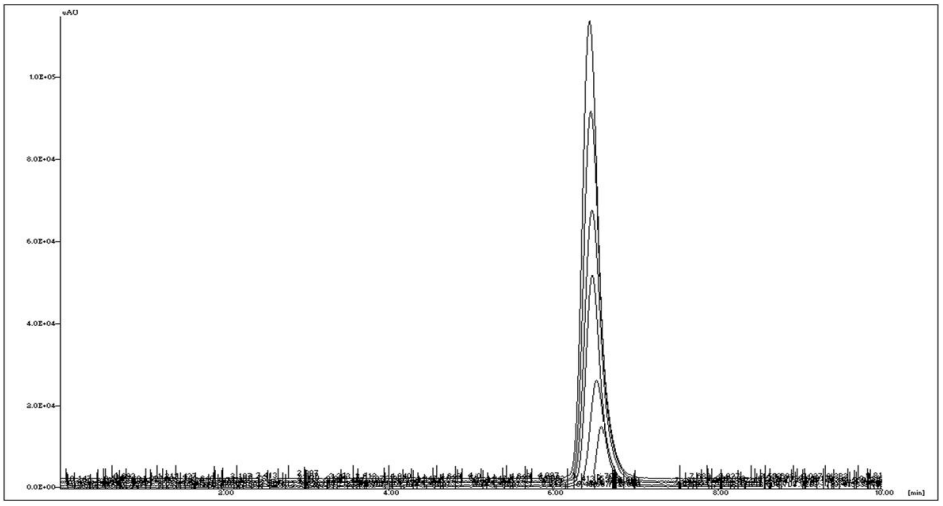

Figure 4: Overlay Chromatogram of assay of Maribavir (10µg/ml)

Table 3 Analysis of Marketed formulation.

Sr. No.	Peak Area	Amount Recovered (µg/ml)	%Recovery	Mean ± % RSD
1	630096.811	3.999	99.976	100.465 ± 0.492
2	631132.304	4.007	100.176	
3	632622.668	4.019	100.465	
4	636052.509	4.045	101.129	
5	635376.191	4.040	100.998	
6	630464.508	4.002	100.047	

With RP-HPLC, the amount of drug in the commercial formulation was determined. It was discovered that the amounts of Maribavir were 100.465 %, respectively. The routine analysis of Maribavir can be done with this approach. Table 3 presents the assay result for the marketed formulation.

3.3 VALIDATION OF RP-HPLC METHOD: [9-11]

3.3.1. Linearity: Various concentration of solution prepared for Linearity of Maribavir are shown in Table 4 calibration curves are shown in Figure 5 respectively.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 7, July 2025 ijppr.humanjournals.com ISSN: 2349-7203

Table 4: Linearity dilutions for Maribavir.

Replicates	Concentrations of Maribavir					
	2 µg/ml	4 µg/ml	6 µg/ml	8 µg/ml	10 µg/ml	12 µg/ml
	Peak Area					
1	332627.760	662887.716	900896.511	1158192.900	1396784.549	1644321.681
2	330454.953	660856.720	908936.697	1163063.624	1393879.373	1659395.318
3	335512.132	676567.949	919038.227	1161957.120	1417223.393	1677040.497
4	330807.105	660496.109	900896.586	1134149.868	1391439.850	1628008.497
5	329336.672	664149.284	880662.130	1150427.939	1419252.021	1649989.206
6	330982.216	677329.150	915246.306	1157519.534	1361191.158	1648090.089
Mean	331620.140	667047.821	904279.409	1154218.497	1396628.391	1651140.881
Std. Dev.	2181.869	7788.469	13714.585	10788.267	21101.103	16316.667
%RSD	0.658	1.168	1.517	0.935	1.511	0.988

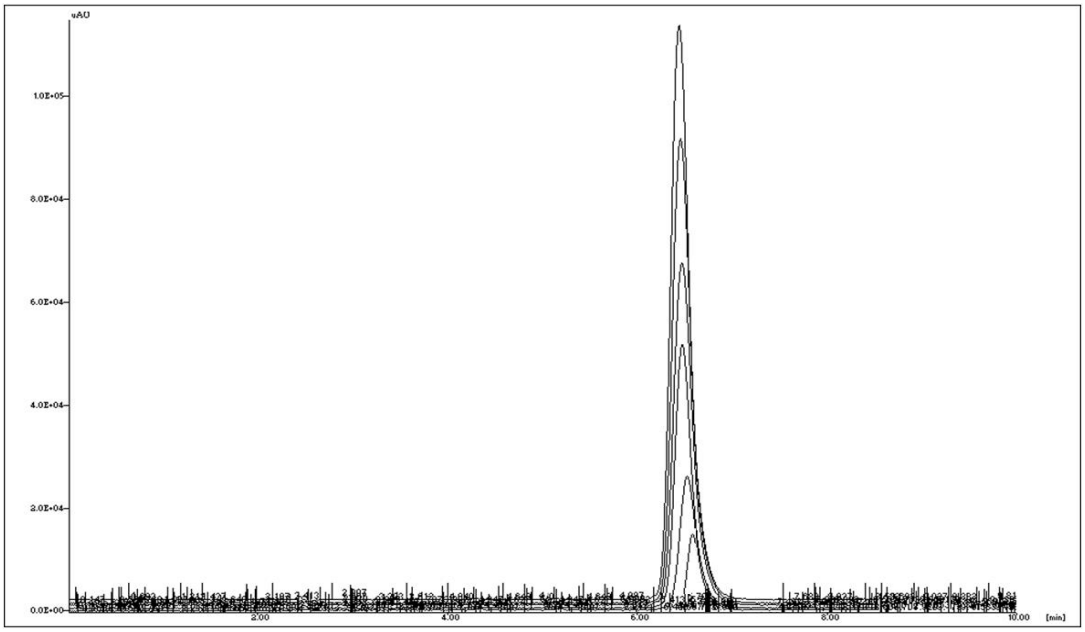

Figure 5 : Overlay of Linearity range (2-12 µg/ml)

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 7, July 2025 ijppr.humanjournals.com ISSN: 2349-7203

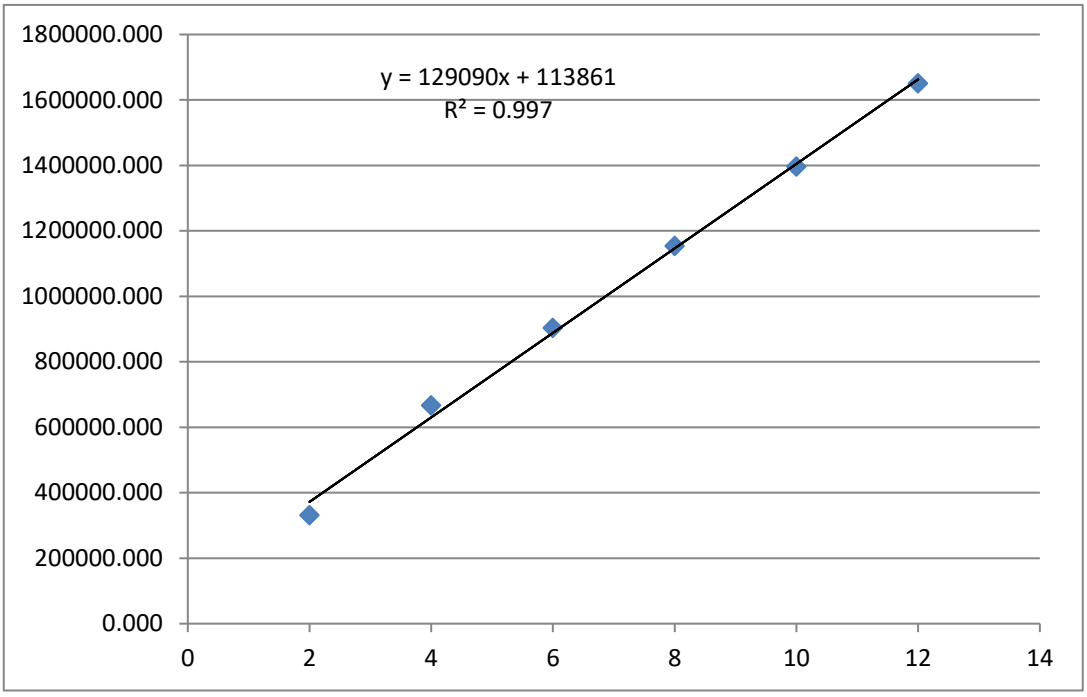

Figure 6: Calibration curve of Maribavir (2-12 µg/ml)

A series standard solution of Maribavir were prepared in the concentration range of 2 µg/ml to 12 µg/mL shown in Table 4.The regression coefficient (r^2) of Maribavir was found to be 0.997. The equation of regression line for Maribavir was found to be y=129090x + 113861 Linearity graph of Maribavir shown in figure 6 respectively.

3.3.2. Precision: The Precision study of Maribavir are shown Table 5 and 6 respectively.

Table 5 Intra Day Precision of Maribavir.

Sr. No.	Theoretical conc.(µg/ml)	Area	Practical Conc. (µg/ml)	%Drug Content	AVG	SD	%RSD
1	**4**	636043.586	4.045	101.128			
2	**4**	640162.301	4.077	101.925	101.299	**0.560**	**0.553**
3	**4**	634582.832	4.034	100.845			
4	**8**	1153692.851	8.055	100.689			
5	**8**	1138031.680	7.934	99.172	100.398	**1.110**	**1.105**
6	**8**	1160350.589	8.107	101.333			
7	**10**	1397575.066	9.944	99.443			
8	**10**	1393649.132	9.914	99.139	99.642	**0.627**	**0.629**
9	**10**	1409202.099	10.034	100.344			

Table 6 Inter Day Precision of Maribavir.

Sr. No.	Theoretical conc. (µg/ml)	Area	Practical Conc. (µg/ml)	%Drug Content	AVG	SD	%RSD
1	4	635600.604	4.042	101.042			
2	4	632619.138	4.019	100.464	100.760	0.289	**0.287**
3	4	634221.467	4.031	100.775			
4	8	1142972.737	7.972	99.651			
5	8	1154565.824	8.062	100.773	99.797	0.912	**0.914**
6	8	1135905.626	7.917	98.966			
7	10	1410752.070	10.046	100.464			
8	10	1402507.907	9.983	99.825	100.118	0.323	**0.322**
9	10	1405610.231	10.007	100.066			

The lower value of standard deviation shows that the technique was specific and percentage relative standard deviation for the intraday 0.553 & 1.105 and interday precision obtained were in the range of 0.287 & 0.914 and showed in Table.5 and 5. It lies within the prescribed limit of less than 2 % at each wavelength. The low value of percentage relative standard deviation reveals the suggested techniques were accurate and precise.

3.3.3.. Accuracy: The accuracy study of Maribavir are shown in

Table 7.Accuracy Study of Maribavir.

Level	Conc. of Sample solution (µg/ml)	Conc. of Standard solution spiked (µg/ml)	Area	Amount recovered (µg/ml)	% Recovery	% Recovery (Mean ± %RSD)
50 %	4	2	889482.524	6.008	100.140	99.971 ± 0.146
			887535.148	5.993	99.888	
			887519.534	5.993	99.886	
100 %	4	4	1153096.304	8.050	100.631	100.327 ± 0.981
			1138595.517	7.938	99.227	
			1158192.851	8.090	101.124	
150 %	4	6	1403727.161	9.992	99.920	100.175 ± 0.274
			1410761.911	10.046	100.465	
			1406570.338	10.014	100.140	

As per the ICH guidelines the mean % Recovery of the Maribavir was found to be in the range of 99.917- 100.327% w/w, it lies within limit of 97-103 % w/w. % Recovery data were obtained in Table 7. The standard addition methods of three different levels were tried 50 %, 100 % and 150 %.

3.3.4. Limit of Detection (LOD) and Limit of Quantification (LOQ):

The LOD and LOQ of Maribavir are shown in Table 8.

Table 8. The LOD and LOQ of Maribavir.

Sr.No	Parameter	Concentration(µg/ml)
1	LOD	0.213 µg/ml
2	LOQ	0.644 µg/ml

The method's sensitivity was assessed in relation to both the limit of Quantitation and the limit of detection (LOD). The lowest amount of analyte in a sample that can be detected is known as the limit of detection, and the lowest amount of analyte in a sample that can be quantitatively quantified with appropriate precision and accuracy is known as the limit of Quantitation, according to ICH

recommendations. LOD and LOQ value for Maribavir was found to be 0.213 µg/mL and 0.644 µg/mL, respectively. Results are shown in Table 8.

3.3.5. Robustness: Robustness data of Maribavir given in below.

Table 9 Robustness parameter of Maribavir.

% RSD Found for Robustness Study (Peak Area)		
DETECTION WAVELENGTH (± 1 nm)		
238nm	239 nm	240 nm
669282.767	663827.513	641679.735
665542.958	657276.432	637455.328
676633.311	659230.036	636533.786
670486.345	660111.327	638556.283
5642.290	3363.283	2743.952
0.842	0.510	0.430
FLOW RATE(± 0.05 ml/min)		
0.75	0.8	0.85
673443.478	659229.196	666712.086
666793.592	647170.867	657633.028
652042.392	646962.066	655814.304
664093.1539	651120.7097	660053.1394
10953.123	7022.931	5838.075
1.649	1.079	0.884
MOBILE PHASE COMPOSITION (± 2 ml)		
78;22	80:20	82;18
663948.872	670229.309	666113.495
658587.213	667731.280	658213.714
669983.839	664450.517	656704.154
664173.308	667470.3686	660343.7876
5701.627	2898.218	5053.398
0.858	0.434	0.765

Robustness was investigated using Change in detection wavelength, Flow rate and varying mobile phase composition in Maribavir. As a result, it is strong and adheres to ICH criteria. Results are shown in Table 9.

4. Forced Degradation Studies

Table 10: Summary of stressed degradation Study.

Sr.No.	Parameter and Condition	% Recovery	% Degradation	RT of degraded products
1	**Acid hydrolysis (1 N HCl for 24 Hr.)**	85.34	14.66	DP1 – 2.928 min
2	**Alkaline Hydrolysis (1 N NaOH for 24 Hr.)**	78.42	21.58	DP1- 2.924 min DP2 – 5.218 min
3	**Oxidative Degradation (30 % w/v H_2O_2 for 24 Hr.)**	92.17	7.83	DP3 – 3.864 min
4	**Thermal degradation (60˚C for 8 Hr.)**	98.73	1.27	--
5	**Photo degradation (UV light200 Watt hours/square meter followed by fluorescence light of NLT 1.2 million Lux-Hr)**	99.14	0.86	--

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4.1 Acid Catalyzed Hydrolysis Degradation

Sample was made by adding 1 ml of 1 N HCl to 1 ml stock solution (1000 µg/ml) of Maribavir. Solution was placed at room temperature for about 24 hour. Solution was then neutralized and volume made to 10 ml with mobile phase and injected to system. Chromatogram was shown in Figure 7.

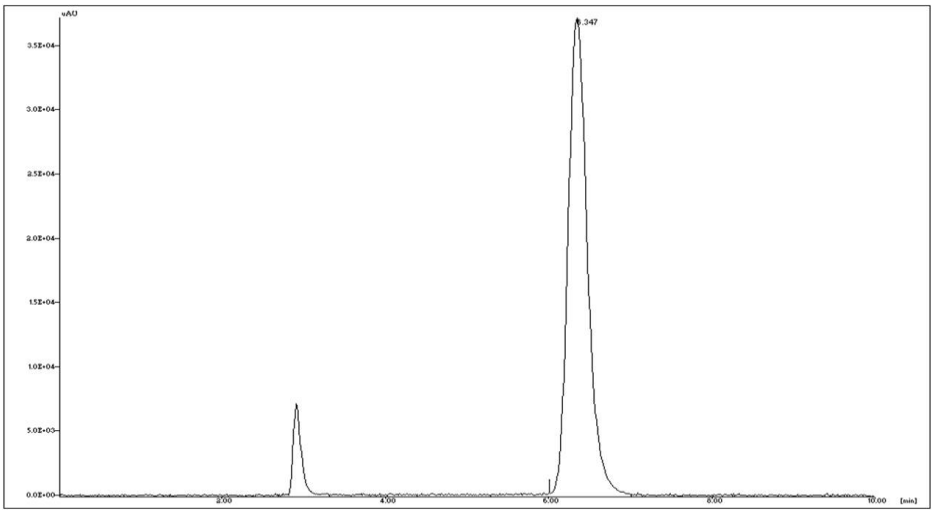

Figure 7: Acid hydrolysis Chromatogram of Maribavir

- **Alkali Catalyzed Hydrolysis Degradation:**

Sample was made by adding 1 ml of 1 N NaOH to 1 ml stock solution (1000 µg/ml) of Maribavir. Solution was placed at room temperature for about 24 hour. Solution was then neutralized and volume made to 10 ml with mobile phase and injected to system. Chromatogram was shown in Figure 8.

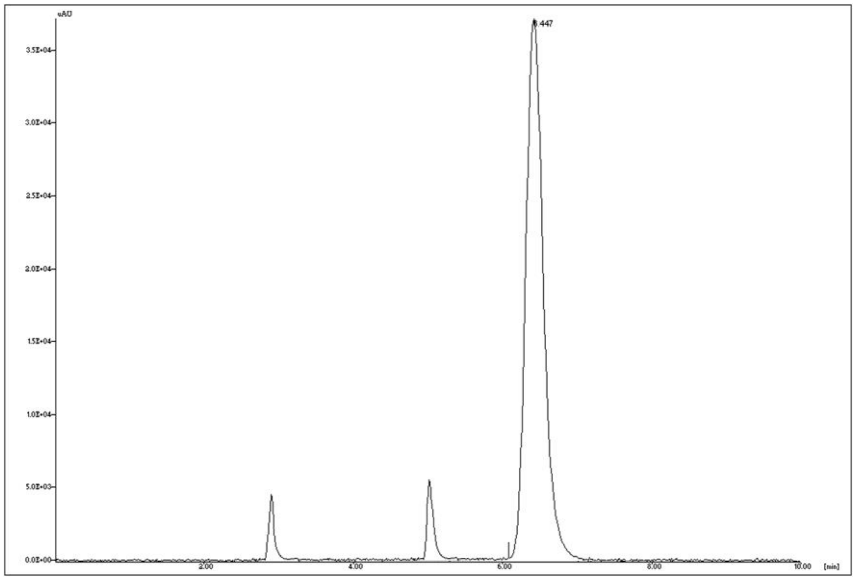

Figure 8 Alkali hydrolysis Chromatogram of Maribavir

- **Hydrogen-Peroxide Induced Degradation:**

Sample was made by adding 1 ml of 30 % w/v H_2O_2 to 1 ml stock solution (1000 µg/ml) of Maribavir. Solution was placed at room temperature for about 24 hour. Volume was then made to 10 ml with mobile phase and injected to system. Chromatogram was shown in Figure 9.

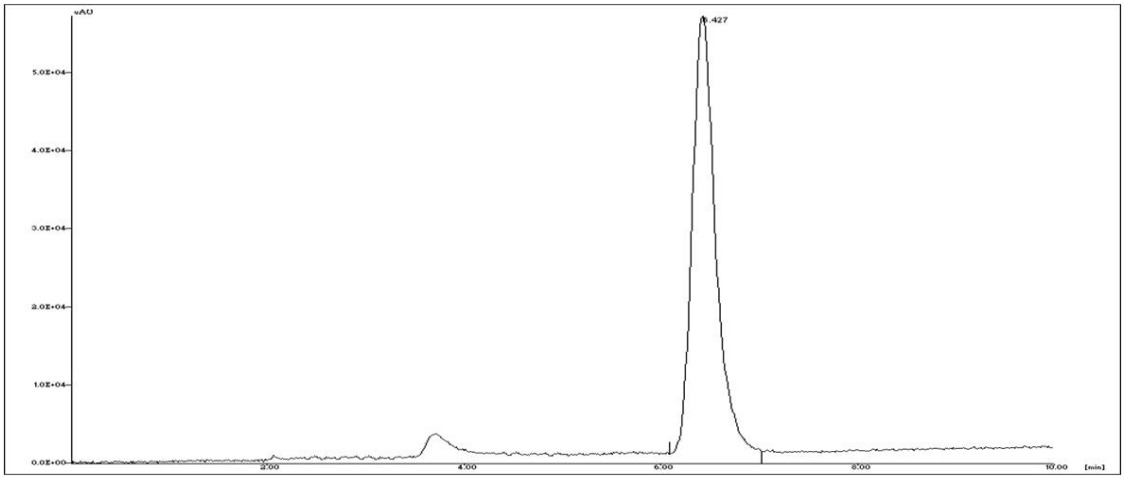

Figure 9: Oxidative hydrolysis Chromatogram of Maribavir

- **Thermal Degradation:**

Bulk drug powder was exposed to 60°c temperature in hot air oven for 8 hour. The sample was cooled to room temperature and then 10 mg of powder was weighed and dissolved in acetonitrile to 10 ml. Diluted with mobile phase and injected to system and chromatogram was recorded. Chromatogram is shown in Figure 10.

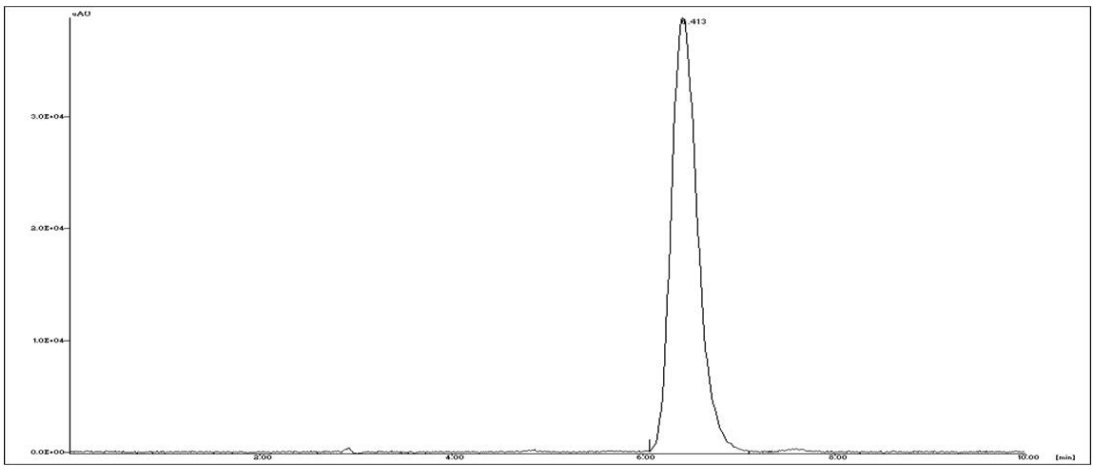

Figure 10: Thermal degradation Chromatogram of Maribavir

- **Photolytic degradation:**

Sample was exposed to UV light for not less than 200-watt hours/square meter followed by white fluorescent light of illumination for not less than 1.2 million lux hours. After exposure 10 mg of powder was weighed and dissolved in acetonitrile to 10 ml. From this final dilution of concentration 100µg/ml was prepared and injected to get chromatogram. Chromatogram was shown in Figure 11.

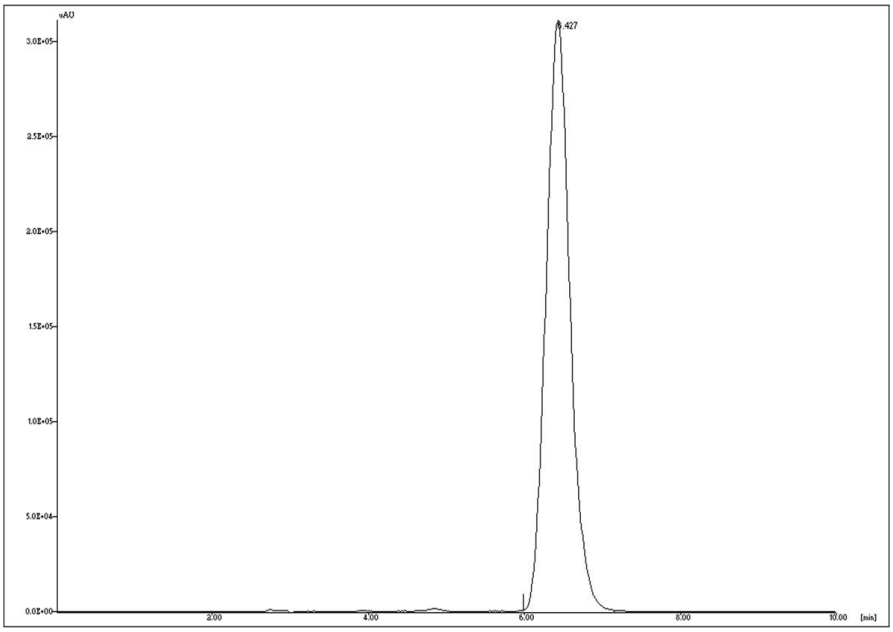

Figure 11. Photo degradation Chromatogram of Maribavir

Conclusion :

Development and validation of RP-HPLC method was found to be linear, accurate, precise, specific and robust according to acceptance criteria and with high level of LOD and LOQ. The results show that the HPLC method presented here can be considered suitable for the analytical determination of Maribavir in bulk and tablet dosage form. The developed method was validated. The good percentage recovery in tablet forms suggests that the excipients present in the dosage forms have no interference in the determination. The %RSD was also less than 2% showing a high degree of precision of the proposed method. The method was successfully applied to the available marketed formulation without any interference due to the excipients and can have an application in the industry. The forced degradation of Maribavir has suggested that the method is stable at different conditions of temperature and humidity.

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