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DEVELOPMENT OF A NEW RP-UPLC METHOD FOR THE ASSURANCE OF RABEPRAZOLE SODIUM IN TABLETS

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Abstract:
A simple, quick and sensitive RP-UPLC method has been developed for the quantitative estimation of Rabeprazole Sodium in bulk and pharmaceutical formulation. The mobile phase 10mM potassium dihydrogen phosphate buffer (pH 7.4 and acetonitrile in the ratio of 65:35 (v/v) at the flow rate of 0.4 ml/min . A waters acquity BEH C18 (50mm × 2.1 mm, 1.7 µ particle size) column was used as stationary phase. The retention time of rabeprazole sodium was 1.49 min. Linearity was observed in the concentration range of 0.03 to 30 µg/ml with good linearity response greater than 0.999. The mean % recovery obtained is 99.1 %. The results of validation suggest that the developed RP-UPLC method could be employed successfully for the estimation of Rabeprazole Sodium in routine analytical work.

Keywords: *Rabeprazole Sodium, RP-UPLC, validation.*

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INTRODUCTION:

Rabeprazole sodium is a proton pump inhibitor with exercises and usages like omeprazole. It is given orally as enteric-secured rabeprazole tablets and regularly taken in the morning [1,2]. For the treatment of genuine ulcerative gastro-oesophageal reflux desease, the standard estimation is 20 mg once step by step for 4 to two months [3,4]. In the USA, a further 8-week course is taken into account the recovering of erosive oeophagitis. Rabeprazole is 2-[{(4)3-methoxy-propoxy-3-methyl-2-pyridinyl} sulphinyl]1-H benzimidazole, its structure is showed up in Figure .1.

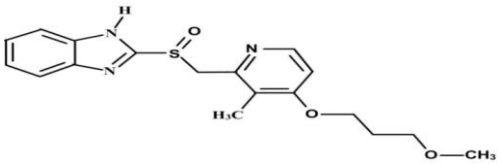

Fig1: Chemical structure of rabeprazole (MF: $C_{18}H_{21}N_3O_3S$, MW: 360)

EXPERIMENTAL:

Materials and Reagents

Standard rabeprazole sodium was gotten as a blessing from Metro Labs Ltd (Baddi, India). Rabeprazole sodium tablets were obtained from a nearby drug store (Pepraz, 10 mg, East West Parma, India). Acetonitrile was bought from Merck (Mumbai, India). High virtue water was gotten utilizing Millipore Milli-Q water cleansing framework [5,6].

Instrumentation

The HPLC framework was a Waters 2695 twofold pump in addition to auto sampler and a 2996 photograph diode cluster and additionally 2487 UV indicator (Waters Corporation) was utilized for all technique development and validation [7,8].

The UPLC analysis was performed on a Waters Acquity UPLC framework (Waters Corporation, Milford, USA) outfitted with a parallel dissolvable director, an auto sampler, and a section chief comprising of a segment broiler and a UV indicator.

Preparation of Standard solutions.

A stock arrangement of 1.0 mg/mL was set up by dissolving a fitting measure of rabeprazole sodium in 10 mM potassium hydroxide arrangement. A working arrangement of 10 µg/mL was set up from this stock arrangement by serial weakening [9].

Preparation of Test Solution from Tablets

Twenty tablets were weighed and powdered. Powder proportional to 50 mg of rabeprazole sodium was exchanged to a 100 mL volumetric cup and separated with 10 mM potassium hydroxide answer for 10 min. The arrangement was weakened reasonably to 10 µg/mL and separated through a 0.45 µm Millipore nylon channel paper [10].

Dissolution Sample Preparation

The disintegration test took after the methodology stipulated by the United States Pharmacopeia USP (711) utilizing mechanical assembly 2 with oars. The oar speed was 100 rpm and reaming disintegration conditions were taken after according to US FDA suggestions. Amid disintegration, the temperature of the media was kept up at 37 ± 0.5°C. For postponed discharge rabeprazole sodium tablets, the US FDA suggests a disintegration test in 700 mL of 0.1 N HCl for 2 hours (Samples were gathered for the estimation of rabeprazole sodium), after which 300 mL of 0.6 M Tris-HCl cradle (pH 8.0) was added to the medium and the disintegration test was proceeded for 45 min (Samples were gathered for the estimation of rabeprazole sodium) [11,12]. Auto examining was utilized to gather 10 mL tests at interims over the trial. The examples were instantly separated through a 0.45 µm Millipore nylon channel. The initial 2 mL test was disposed of before accumulation of the specimens for analysis [13].

Optimization of Chromatographic Method

The primary point of the created technique was to accomplish partition and measurement of rabeprazole utilizing an isocratic versatile stage with an UPLC framework. The UPLC strategy was created to diminish the run time of the technique and dissolvable utilization for routine analysis, for example, measure, disintegration and substance uniformity amid quality confirmation. Recognition of rabeprazole was satisfactory at 280 nm. The underlying trial was led utilizing HPLC and chromatographic partition was acquired on Waters symmetry C18 section (150 x 4.6 mm, 5 micron). Rabeprazole is a corrosive labile compound and to maintain a strategic distance from any debasement, a versatile stage with essential pH was chosen. The portable stage was upgraded in the proportion of 10 mM potassium dihydrogen phosphate cushion (pH 7.4, balanced with potassium hydroxide arrangement) to acetonitrile of 65:35 (v/v) with a stream rate of 1.0 mL/min and infusion volume 20 µL.

While building up the UPLC strategy, fundamental chromatographic states of the HPLC technique, as far as segment, solvents and UV discovery, were taken after. In selecting the UPLC segment, its dependability at the higher pH was thought about to safeguard the section's long life. For rabeprazole sodium, the prescribed FDA media for disintegration arrangement studies is pH 8.0. The

enhanced versatile stage pH utilized as a part of the present review is likewise on the essential side. Most business C18 sections are not steady at high pH on the more drawn out run, which brings about shortening their life expectancy. Waters Acquity BEH C18 (50 mm x 2.1 mm, 1.7 micron) segment was observed to be more appropriate and stable at a pH of 8.0. The pinnacle was sharp and adequate and the infusion volume was diminished from 20 to 5 µL. The stream rate likewise downsized from 1.0 to 0.4 mL/min.

At the point when these working conditions were connected to the created technique, an agreeable pinnacle was accomplished for rabeprazole, which eluted at around 1.49 min, giving an aggregate run time of 2 min. The advanced UPLC chromatographic condition is appeared in Table 1.

An examination amongst HPLC and UPLC with respect to elution time, affectability and other chromatographic parameters after the infusion of standard arrangement is appeared in Table 2. The outcomes show that the elution time of rabeprazole in UPLC was decreased by around 9-overlay contrasted with that of HPLC. Hypothetical plates got for UPLC are around 8-overlap higher contrasted with that of HPLC. This demonstrates the higher partition productivity of UPLC when contrasted with HPLC. The UPLC and HPLC correlation chromatograms are appeared in Figures 2 & 3.

Table 1: Optimized UPLC chromatographic conditions

Buffer	10 mM potassium dihydrogen phosphate buffer, pH adjusted to 7.4 with potassium hydroxide solution
Mobile phase	Mixure of buffer and acetonitrile (65:35, v/v)
Diluent	10 mM potassium hydroxide solution
Column oven	Ambient temperature
Column	Waters Acquity BEH C_{18}, 50 mm x 2.1 mm, 1.7 micron
Detection wavelength	280 nm
Injection volume	5 µL
Flow rate	0.4 mL/min

Table:2 Comparative working parameters of HPLC and created UPLC methods

System	Flow rate (mL/min)	Injection volume (µL)	USP tailing	USP plates count	Elution time (min)
UPLC	0.4	5	1.2	44790	1.49
HPLC	1.0	20	1.5	4700	12.72

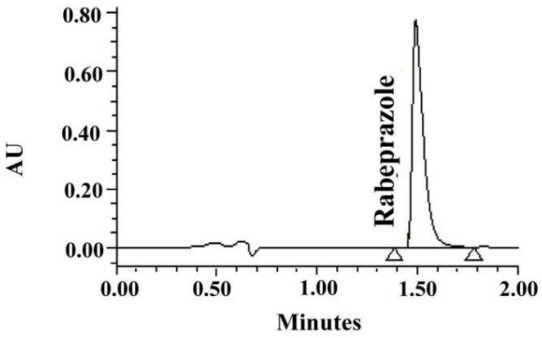

Fig 2: UPLC chromatogram of standard

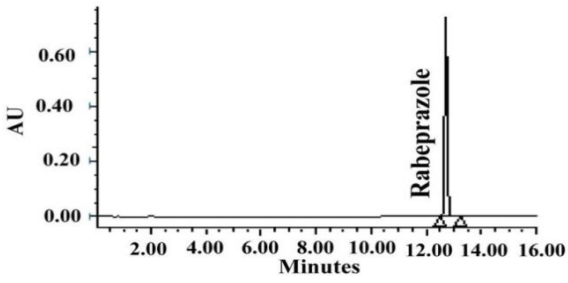

Fig 3: HPLC chromatogram of standard

Method Validation

Linearity

Levels of analyte fixation (0.03, 0.5, 1.0, 5.0, 7.5, 10.0,12.5, 15.0, 20.0 and 30.0 µg/mL). The pinnacle range versus fixation information was dealt with by slightest squares direct relapse analysis. The linearity of the alignment plot for the strategy was acquired over the adjustment ranges tried, i.e., 0.03 µg/mL to 30 µg/mL and the connection coefficient got was > 0.999. This showed brilliant relationship between's pinnacle ranges and centralizations of the analyte. The relapse condition is Y Rabeprazole sodium = 705304x - 23709 (r2 = 0.9999).

Precision

The precision of the method was evaluated by carrying out six independent assays of test samples against a qualified reference standard and the RSD of assay was calculated. The intermediate precision of the method was also evaluated using different analysts, columns (Different lot of Waters Acquit BEH C_{18} [50 x 2.1 mm, 1.7 micron]) and instruments (Different UPLC system of Waters Acquity) in the same laboratory.

Table 3: Precision readings

Injection	Method precision Assay (%)	Intermediate precision Assay (%)
1	99.1	98.1
2	98.0	98.5
3	98.3	99.1
4	98.1	100.8
5	101.1	100.5
6	100.3	99.3
Average	99.2	99.4
% RSD	1.3	1.1

The % RSDs of rabeprazole sodium assay during the method precision and the intermediate precision were 1.3 and 1.1 respectively, indicating good precision of the method. The results are shown in Table 3.

Accuracy

The accuracy of the assay method was evaluated in a triplicate at six concentration levels (between 10 % and 150 %), i.e., 1.0, 3.0, 5.0, 7.5, 10.0 and 15.0 µg/mL. Percent recoveries were calculated. Percent recovery of rabeprazole sodium ranged from 98.0 % to 101.5 and % RSD values were within 1.3 %, showing the method's good accuracy.

Robustness

To determine the robustness of the developed method, experimental conditions were deliberately altered and system suitability parameters were checked. The flow rate of the mobile phase was 0.4 mL/min. To study the effect of flow rate, it was changed by 0.05 units from 0.35 mL/min to 0.45 mL/min. The proportion of acetonitrile in the mobile phase (35 %) was changed by ± 3.5 % and the UV detection wavelength (280 nm) was changed by 3 nm. To study the effect of pH variation in the mobile phase, pH was altered by ± 0.2 units, i.e., 7.2 and 7.6. Changes in chromatographic parameters, i.e., theoretical plates, tailing factor and % RSD were evaluated for the method. In all the deliberately varied chromatographic conditions, the assay results were between 98 % and 101 %, and no significant changes were obtained in chromatographic parameters. This shows the robustness of the developed method. The results are shown in Table 4.

Table 4: Robustness results

Variations	USP tailing factor	USP theoretical plates	% RSD	% Assay
Flow rate				
0.40 mL/min (original)	44790	1.20	0.67	99.1
0.35 mL/ min	46188	1.17	1.10	98.1
0.45 mL/min	42881	1.21	0.90	101.0
pH				
7.4 (original)	44790	1.20	0.67	99.1
7.2	43112	1.22	1.20	98.0
7.6	45121	1.19	1.25	98.5
Organic composition				
Acetonitrile				
35 %, v/v) (original)	44790	1.20	0.67	99.1
Acetonitrile				
(31.5 %, v/v)	42111	1.25	0.90	100.5
Acetonitrile				
(38.5 %, v/v)	43121	1.21	1.10	98.9
Wavelength				
280 nm (Original)	44790	1.20	0.67	99.1
277 nm	44790	1.20	0.67	99.1
283 nm	44790	1.20	0.67	99.1

Application of the Developed Method

At the point when the created strategy was utilized to investigate a business brand of the rabeprazole sodium tablet formulation, the mean recuperation of six imitates was 99.69 % with a % RSD of 0.52. The percent recuperation esteem demonstrates non-obstruction from the excipients show in the dose form.

Use of the created technique to pulled back rabeprazole sodium tablet disintegration tests, mean discharge in corrosive (pH 1.2) media was 2.8 % (for a normal of 6 tablets) with % RSD of 4.5 and antacid (pH 8.0 support) media was 97.2 % (for a normal of 6 tablets) with % RSD of 3.2. Both the test and disintegration test investigations were performed inside 45 min, demonstrating the analysis' quickness utilizing UPLC technique.

CONCLUSION:

The new, isocratic RP-UPLC strategy ended up being basic, direct, exact, precise, strong, rough and fast. The created strategy is equipped for giving quicker elution and keeping up great detachment more than what was accomplished with traditional HPLC. The short maintenance time of 1.49 min permits the analysis of countless in a brief timeframe and so is more financially savvy for routine analysis in the pharmaceutical businesses. The created technique was effectively connected to the rabeprazole sodium tablet's disintegration examine. It is appropriate for the fast and precise quality control of rabeprazole sodium in tablet formulations.

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