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A NEW VALIDATED RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ESOMEPRAZOLE IN BULK AND PHARMACEUTICAL DOSAGE FORM

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Keywords:

RP-HPLC, Method Development, U.V. Spectroscopy, Validation, Accuracy, Precision, ICH Guidelines.

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ABSTRACT: Reverse Phase High-Performance Liquid chromatography is a widely and commonly used analytical method for qualitative and quantitative analysis. A simple, accurate, economical, rapid, and precise RP-HPLC process has been proposed and validated for the determination of esomeprazole in immense bulk and dispensed pharmaceutical drug form. The RP-HPLC separation was achieved on Symmetry ODS RP C18, 5 µm, 15 mm × 4.6 mm i.d. column using mobile phase Phosphate buffer (pH=3.6): ACN = 50:50 pH Adjudged with Orthophosphoric acid at continuance effusion of 1.0 ml/min at ambient temperature. The retention times were observed at 3.797 min for esomeprazole. The calibration plot is linear beyond the concentration range 0-50 µg/ml for esomeprazole. Quantification was achieved with UV detection at 246 nm over the Beer-Lambert's range. The proposed methodology is validated statistically as per the ICH guidelines for various validation parameters includes, including Accuracy, Precision, Linearity and range, Limit of detection, and Limit of Quantification. The above method is developed and validated successfully for the routine quantitative analysis of esomeprazole in bulk and pharmaceutical dosage form.

INTRODUCTION: Analytical chemistry is employed to determining the qualitative and quantitative composition of the fabric below the study. Both these aspects are necessary to grasp the sample material. Analytical chemistry is split into 2 branches quantitative and qualitative. A qualitative analysis offers us the knowledge regarding. The character of sample by knowing concerning the presence or absence of sure elements. Quantitative chemical analysis provides numerical data on the relative quantity of 1 or a lot of this component [1]. In non-instrumental, the traditional and physicochemical properties are used to investigate the sample.

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The instrumental strategies of research are primarily based upon determining the property of substance-using analytical instrument for determining its composition [2]. Chromatography could be a process employed to separate the elements of the mixture by a continuous distribution of the component between 2 phases.

One section moves (mobile phase) over the opposite phase (stationary phase) continuously. Reverse-phase chromatography is the foremost common mode for analytical and preparatory separations of compound of interest in chemical, biological, pharmaceutical, food and medicine sciences. During this mode, the stationary section is non-polar hydrophobic packing with physic-chemical properties of the drug. Octyl or octadecyl functional cluster secure to silica gel and therefore the mobile phase is polar solvent [3, 4]. The physical and chemical parameters of a drug play a critical role in the development of a new HPLC method. For method development, it is required that one must study the physical properties like solubility, polarity and pKa and hydrogen ion concentration of the drug molecule. Polarity could be a property of a compound.

It helps associate analysts to make a decision on the solvent and composition of the mobile section. In a non-polar bond, the electrons are shared equally between 2 atoms. pH and pKa play a crucial role in HPLC methodology development [5]. These ways are preferred to make sure to recognize chastity, strength as well as the performance of the drug. There are several factors to think about once developing ways. The bulk of the HPLC development goes into supportive a stability-indicating HPLC method. The goal of the HPLC method is to undertake and separate quantify the most active drug, any reaction impurities, all on the market artificial intermediates and any degradants.

The most purpose of holding out the strategy development is that, it builds a degree of confidence and conjointly absorbs the shock of variations of analytical conditions and pays for quite invested with on the method [6]. Validation of the analytical procedure is that the method by which it's standard, by practical studies, that the performance characteristics of the procedure carried meet the necessities for its meant use. The strategies validation method for analytical procedures begins with the planned and systematic assortment by the individual of the validation information to support analytical procedures. All analytical methods that are intended are used for examining any samples will be validated. The complete procedure and involved steps is done as per ICH guidelines [7].

Esomeprazole, sold with the brand Nexium, is a proton pump inhibitor (PPI) medication used for the management of reflux illness (GERD), for internal organ protection to stop repetition of abdomen ulcers or gastric injury from chronic use of NSAIDs. Its effectiveness is taken into account the same as alternative medications inside the PPI category. Esomeprazole exerts its abdomen acid-suppressing effects by preventing the ultimate step in internal organ acid production by covalently binding to sulfhydryl groups of cysteines found on the (H+, K+-ATPase catalyst at the humor surface of viscous membrane bone cells. This impact results in inhibition of each basal and stirred viscous acid secretion, regardless of the stimulant [8, 9]. Elevated intraocular pressure could be a characteristic manifestation of ocular high blood pressure or glaucoma.

The extent of pressure level (IOP) is ruled by the balance between the assembly of humor (by ocular ciliary processes) and its outflow from the anterior section of the eye via trabeculate (conventional) or uveoscleral (unconventional) pathways. Once there's a rise within the resistance to the trabeculate outflow of humor, the pressure level is elevated. Later on, nervus opticus injury will occur from blood flow restrictions and mechanical distortion of ocular structures. Nervus opticus injury will end more in blind spot bloodletting and progressive field of vision loss (and visual impairment in some cases). Esomeprazole is extensively metabolized within the liver by the cytochrome P450 (CYP) catalyst system. The end products of esomeprazole do not have antisecretory functions.

The key part of esomeprazole metabolism relies upon the CYP2C19 isoenzyme, which forms the radical and desmethyl metabolites; the remaining quantity relies on CYP3A4 that forms the sulphone substance [10, 11]. The work plan included to undertake solubility and analytical studies of the drug Esomeprazole and develop initial U.V. and chromatographic conditions followed by setting up initial UV and chromatographic conditions for the method development in pure and pharmaceutical dosage forms. Further followed by, Optimization of initial chromatographic and spectrophotometric conditions. Post-optimization, Analytical method validation of the developed RP- HPLC method is carried out.

MATERIALS AND METHODS:

Materials:

Instruments Used: HPLC waters with UV-Visible Detector, T60 LAB INDIA UV - Vis spectrophotometer, Electronic Balance (SHIMADZU ATY224), Ultra Sonicator (Wensar wuc 2L), Thermal Oven, Develosil ODS HG-(C18) RP Column, 15 mm × 4.6 mm. PH Analyzer (ELICO), Vaccum filtration kit (BOROSIL).

Reagents Used: Doubled distilled water, HPLC Grade water, Ethanol, DMF, of 99.99% purity with HPLC Grade were used, which were supplied by Sd. Fine - Chem. Ltd. Mumbai and Methanol and DMSO of 99.99% purity with HPLC Grade were used which were supplied by Loba Chem. Mumbai.

Methods:

Solubility Study 12: The solubility study of Esomeprazole was carried out using Acetonitrile, Ethanol, DMF, DMSO, Aqueous buffers and water. The observations are tabulated below in **Table 1.**

TABLE 1: SOLUBILITY OF ESOMEPRAZOLE IN VARIOUS SOLVENTS

Solvent	Solubility
ACN	Soluble
Ethanol	Soluble
DMF	Soluble
DMSO	Soluble
Aqueous Buffers	Sparingly Soluble
Water	Slightly Soluble

Mobile Phase: The mobile section employed in this analysis consists of a mix of Phosphate buffer (pH adjusted to 3.6 by orthophosphoric acid) and Acetonitrile during a quantitative relation of 50:50. 500 ml of this solution was superimposed and properly mixed with five hundred cubic centimetres of acetonitrile, and a standardized solution is achieved. Determination of maxima of esomeprazole using UV - Vis spectroscopy [13].

Standard and Sample Preparation: 10 mg of Esomeprazole normal was transferred into a ten millilitre meter flask, dissolved & conjure to volume with solvent. Later on, the concentration is reduced by dilution, which was done by transferring one mil of the higher than solution into a 10 ml volumetric flask and form up to volume with solvent. The normal and sample stock solutions were ready one by one by dissolving normal & sample in an exceedingly solvent by diluting with an equivalent solvent. (After improvement of all conditions) for ultraviolet radiation analysis. This has been performed to understand the maxima of Esomeprazole, in order that an equivalent frequency will be utilized in HPLC ultraviolet radiation detector for estimating the Esomeprazole. Based on the above preparation of standard and sample solutions, **Fig. 1.** depicts the UV Spectra, and the maximum for the drug esomeprazole was found out to be 246 nm.

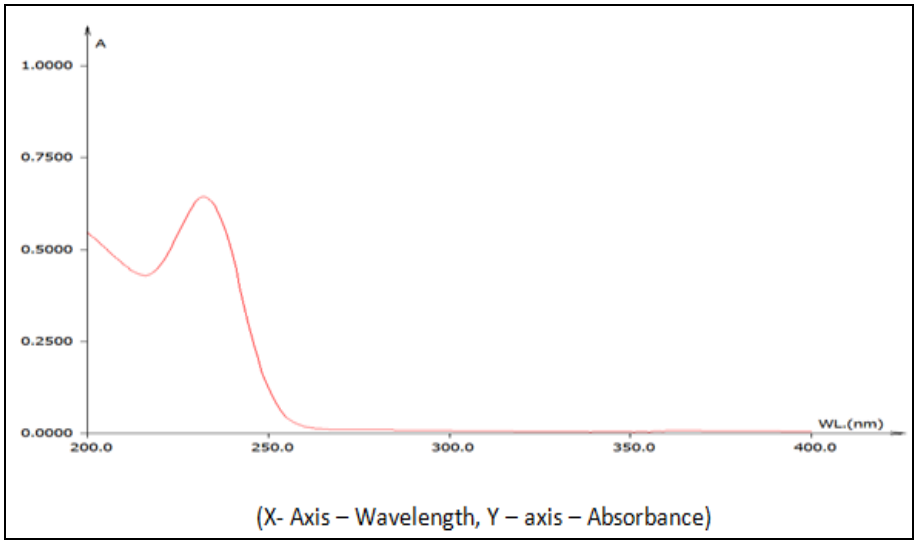

FIG. 1: UV SPECTRA OF ESOMEPRAZOLE FOR MAXIMA DETERMINATION

The maxima for esomeprazole by UV - Vis spectroscopy was found to be 246 nm. Method Development of esomeprazole - Trial 1 (X-axis - Minutes, Y-axis - Voltage)

Method Development of Esomeprazole:

Trial 1: The mobile phase which was selected for this trail is Acetonitrile: Water in the ratio of 30: 70 using the column, Develosil ODS HG-5 RP C18, 5

µm, 15 cm × 4.6 mm i.d, with a flow rate of 0.8 ml/min and wavelength of 246 nm. Take stock of 10 milligrams of Esomeprazole and shift it into 10 mil metric flask, dissolved and make up the volume with the mobile phase. Later on, the concentration is reduced by dilution, which was done by transferring 1 mil of the prepared solution into a 10 ml metric flask and form up the volume with mobile phase [14]. This final solution is utilized for recording the observations. The figure and results are shown in **Fig. 2.** and **Table 2.**

The efficiency of the chromatogram was not satisfactory, and the peak response was very low; hence, this method is not selected for optimization

Method Development of esomeprazole - Trial - 02 (X-axis - Minutes, Y-axis - Voltage)

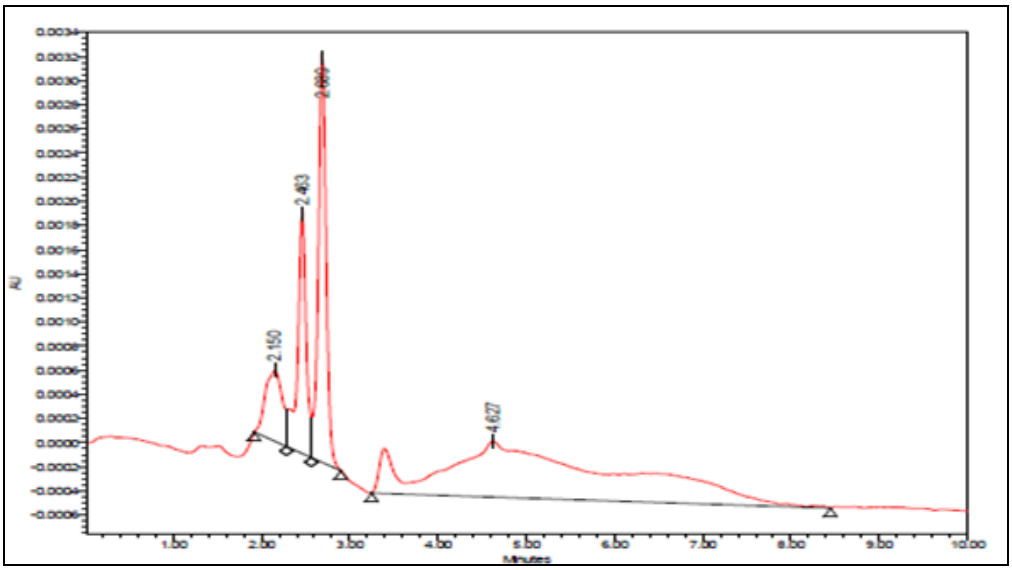

FIG. 2: CHROMATOGRAM - 01 FOR METHOD DEVELOPMENT OF ESOMEPRAZOLE BY RP - HPLC

TABLE 2: PEAK RESULTS

RT	Area	Theoretical Plates	Tailing factor
3.797	1048952	3125	1.02

Trial 2: The mobile phase which was selected for this trail is Acetonitrile: Water in the ratio of 35: 65 using the column, Develosil ODS HG-5 RP C18, 5 µm, 15 cm × 4.6 mm i.d, with a flow rate of 1.0 ml/min and wavelength of 246 nm. Take stock of 10 milligrams of Esomeprazole and shift it into 10 mil metric flask, dissolved and make up the volume with mobile phase. Later on, the concentration is reduced by dilution, which was done by transferring 1 mil of the prepared solution into a 10 ml metric flask and form up the volume with mobile phase [15]. This final solution is utilized for recording the observations. The figure and results are shown in **Fig. 3.** and **Table 3.**

Trial 3: The mobile phase which was selected for this trial is Phosphate buffer of a PH 3.6: Acetonitrile in the ratio of 50: 50 using the column, Develosil ODS HG-5 RP C18, 5 µm, 15 cm × 4.6 mm i.d, with a flow rate of 1.0 ml/min and wavelength of 246 nm. Take stock of 10 milligrams of Esomeprazole and shift it into 10 mil metric flask, dissolved, and make up the volume with the mobile phase. Later on, the concentration is reduced by dilution, which was done by transferring 1 ml of the prepared solution into a 10 ml metric flask and form up the volume with mobile phase [16]. This final solution is utilized for recording the observations. The figure and results are shown in **Fig. 4.** and **Table 4.**

Assay: Twenty tablets were taken, and therefore, the I.P. methodology was followed to work out the common weight. Above weighed tablets were finally fine-grained and triturated well. An amount of powder corresponding to 100 mg of medication were transferred to a 100-millilitre meter flask, and seventy ml of HPLC grade methyl alcohol was superimposed, and the solution was sonicated for a quarter-hour, there when the volume was created up to one hundred ml with the same solvent. Then ten mil of the on top of solution was diluted to one hundred ml with HPLC grade methanol. The solution was filtered through a membrane filter (0.45 µm) and sonicated to degas [17]. From this

stock solution (3.5 ml) was transferred five} different ten mil meter flasks, and volume was created up to 10 ml with the same solvent system. The solution ready was injected in 5 replicates into the HPLC system, and therefore, the observations were recorded. A replica injection of the normal solution was conjointly injected into the HPLC, and there the peak areas recorded [18]. The results are shown in **Table 5.**

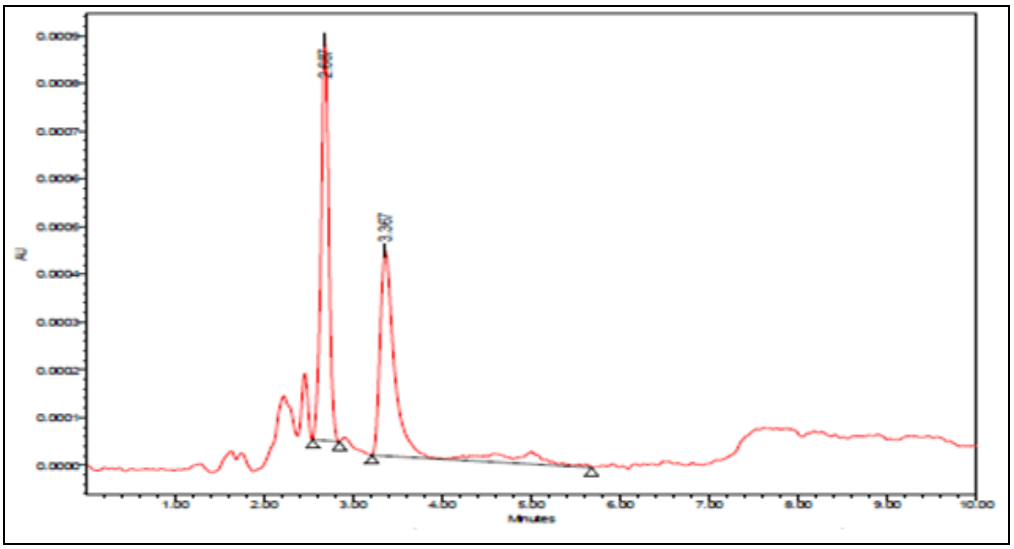

FIG. 3: CHROMATOGRAM – 02 FOR METHOD DEVELOPMENT OF ESOMEPRAZOLE BY RP - HPLC

TABLE 3: PEAK RESULTS

RT	Area	Theoretical Plates	Tailing factor
2.687	1248952	3582	1.28
3.367	1536524	3712	1.06

The efficiency of the chromatogram was not satisfactory, and the dual peaks response have been observed; hence, this method is not selected for optimization

Method Development of esomeprazole – Trial 3: (X-axis - Minutes, Y-axis - Voltage)

TABLE 4: PEAK RESULTS

RT	Area	Theoretical Plates	Tailing factor
3.797	1048952	3125	1.02

The efficiency of the chromatogram was not satisfactory, and the dual peaks response have been observed; hence, this method is not selected for optimization

Method Development of esomeprazole - Trial 3: (X-axis - Minutes, Y-axis - Voltage)

Validation 19:

System Suitability: System suitability testing is an integral part of several analytical procedures. The conception supports the tests that the instru-mentation, analytical operations, and samples to be analyzed represent an integral system that may be evaluated in and of it. The results are shown in **Table 11.**

Accuracy: To determine the accuracy of the planned methodology, recovery studies were carried out by adding totally different amounts (80%, 100%, and 120%) of pure drug of Esomeprazole were taken and value-added to the pre-analyzed formulation of concentration 50 µg/ml. From that, percentage recovery values were calculated. The results are shown in **Table 6.**

Precision:

Repeatability: The precision of each methodology was determined one by one from the peak areas and retention times obtained by actual determination of six replicates of a set quantity of the drug. Esomeprazole (API). The % relative normal deviations were calculated for Esomeprazole. The results are shown in **Table 7.**

Intermediate Precision: The Intermediate Precision Consists of 2 Methods. Intraday in the Intra Day method, the 40%, 50%, and 60% concentrations are injected at completely different intervals of time in same day. Inter Day: In inter Day method; the 40%, 50% and 60% concentration are injected at same intervals of time in different days. The results are shown in **Table 8.**

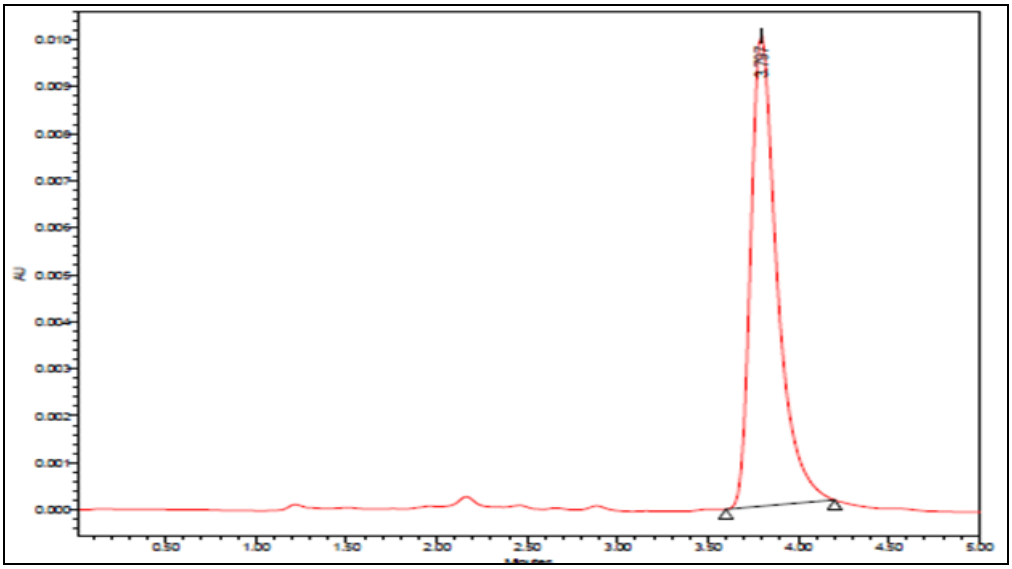

FIG. 4: CHROMATOGRAM - 03 FOR METHOD DEVELOPMENT OF ESOMEPRAZOLE BY RP - HPLC

TABLE 5: RESULTS OBTAINED FROM ASSAY OF ESOMEPRAZOLE BY HPLC

Brand name of Injection	Labelled amount of Drug (mg/ml)	Mean (±SD) amount (mg/ml) found by the proposed method (n=6)	Assay + % RSD
Nexium(20mg/ml)	20	19.91 (±0.05)	99.55 (±0.68)

Here the peaks were separated and showed better resolution, theoretical plate count, and symmetry. The proposed chromatographic conditions were found appropriate for the quantitative determination of the drug.

Assay: The amount of drug in Nexium (20 mg/ml) Injection was found to be 19.91 ± 0.05) mg/tab for Esomeprazole and % assay was 99.55%.

Method Validation:

Accuracy: From the Accuracy Method, we observed that the %Recovery of the drug is within the range of 98-102% *i.e.,* 99.448%, 100.388%,100.596%. And the % RSD is <2 *i.e.*1.812323%, 0.629776%% and 1.700836% respectively.

Linearity & Range: To assess the linearity, serial dilution of analyte were ready from the stock solution was diluted with mobile section to induce a series of concentrations starting from 20-70 µg/ml. The prepared solutions were filtered through Whatman paper (No.41). From these solutions, 10 µl injections of every concentration were injected into the HPLC system and chromate was graphed below the optimized conditions. A calibration curve was made by plotting the mean peak area (Y-axis) against the concentration (X-axis). The figure and results are shown in **Fig. 5.** and **Table 9.**

TABLE 6: RESULTS OBTAINED FROM ACCURACY OF ESOMEPRAZOLE (% RECOVERY AND STATISTICAL ANALYSIS)

S. no	Pure drug	Peak Area	Conc Found	% Recovery of Pure drug	Statistical analysis
S_1 : 80 %	40	251621	39.3753	98.43826	Mean= 99.448%
S_2 : 80 %	40	251465	39.35089	98.37722	S.D. = 1.0823199
S_3 : 80 %	40	259521	40.61161	101.529	R.S.D.= 1.812323%
S_4 : 100 %	50	318512	49.84338	99.68675	Mean= 100.388%
S_5 : 100 %	50	321312	50.28156	100.5631	S.D. = 0.63222
S_6 : 100 %	50	322434	50.45715	100.9143	R.S.D.= 0.629776%
S_7 : 120 %	60	381475	59.69674	99.49457	Mean= 100.596%
S_8 : 120 %	60	382365	59.83602	99.7267	S.D. = 1.710973
S_9 : 120 %	60	393256	61.5404	102.5673	R.S.D. = 1.700836%

Method Robustness: Influence of minor changes in chromatographic parameters reminiscent of modification in rate of flow (± 0.1 ml/min), Wavelength of detection (± 2 nm) & organic section content in the mobile phase (± 2%) studied to work out the hardiness of the strategy are also in

favour of the developed RP-HPLC technique for the analysis of Esomeprazole (API). The results are shown in **Table 10.**

Limit of Detection and Limit of Quantification (LOD & LOQ): 20

The detection limit of a private analytical procedure is that the lowest quantity of analyte may be detected, however not essentially quantitated as a precise worth. The limit of quantitation is outlined because of the lowest concentration of associate.

Analyte which will be determined with acceptable preciseness and accuracy underneath the explicit operational conditions of the method.

TABLE 7: RESULTS OBTAINED FROM PRECISION OF ESOMEPRAZOLE (STANDARD DEVIATION AND % RSD)

HPLC Injection Replicates of Esomeprazole	Retention Time	Area
Replicate – 1	3.797	106134
Replicate – 2	3.799	105762
Replicate – 3	3.801	103536
Replicate – 4	3.802	105762
Replicate – 5	3.805	101767
Replicate – 6	3.803	103256
Average	3.801166667	10436986.5
Standard Deviation	0.002857738	177195.3912
% RSD	0.07518	1.697763921

Precision - Repeatability: From the Precision method, we observed that the % RSD of the AUC is 1.697763921 and RT is 0.07518, which are within the acceptable range as per ICH guidelines.

TABLE 8: RESULTS OBTAINED FROM INTERMEDIATE PRECISION OF ESOMEPRAZOLE (INTRADAY AND INTERDAY)

Conc. Of Esomeprazole (API) (µg/ml)	Observed Conc. Of Esomeprazole (µg/ml) by the proposed method			
	Intra-Day		Inter-Day	
	Mean (n=6)	% RSD	Mean (n=6)	% RSD
40	39.8	0.39	37.8	0.38
50	59.8	0.58	59.7	0.57
60	60.01	0.60	60.19	0.61

Intermediate precision: The intra & inter-day variation of the method was carried out & the high values of mean assay & low values of standard deviation & % RSD (% RSD < 2%) within a day & day to day variations for Esomeprazole revealed that the proposed method is precise.

Linearity and Range:

TABLE 9: RESULTS OBTAINED FROM LINEARITY OF ESOMEPRAZOLE

CONC.(µg/ml)	MEAN AUC (n=6)
0	0
30	189804
40	248924
50	318701
60	390994
70	441497

Linearity and Range: We observed that the curve showed good linearity in the range of 10-50 µg/ml, for Esomeprazole (API) with a correlation coefficient (R2) of 0.999. A typical calibration curve has the regression equation of y = 6390 × + 1282 for Esomeprazole.

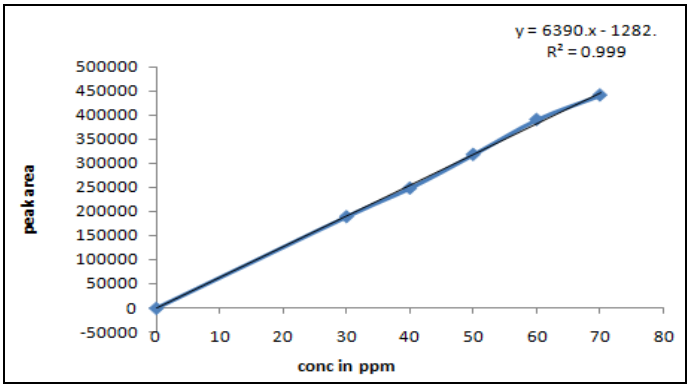

FIG. 5: LINEARITY GRAPH OF ESOMEPRAZOLE

RESULTS AND DISCUSSIONS

Determination of Maxima of Esomeprazole Using UV - Vis Spectroscopy:

Method Robustness:

TABLE 10: RESULTS OBTAINED FROM METHOD ROBUSTNESS OF ESOMEPRAZOLE

Change in parameter	% RSD
Flow (1.1 ml/min)	0.35
Flow (0.9 ml/min)	0.39
More Organic	0.16
Less Organic	0.09
Wavelength of Detection (248 nm)	0.27
Wavelength of detection (244 nm)	0.37

System Suitability:

TABLE 11: SYSTEM SUITABILITY PARAMETERS RESULTS OF ESOMEPRAZOLE

S. no	Parameter	Limit	Result
1	Resolution	Rs > 2	9.15
2	Asymmetry	T ≤ 2	Esomeprazole=0.12
3	Theoretical plate	N > 2000	Esomeprazole=3246

CONCLUSION: A sensitive & selective RP-HPLC method has been developed and validated to analyze esomeprazole API. Further, the proposed RP-HPLC method has excellent sensitivity, precision, and reproducibility.

The result shows the developed method is yet another suitable method for assay purity, which can help analyze esomeprazole in different formulations.

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CONFLICTS OF INTEREST: The authors declare no conflicts of interest.

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