RP-HPLC Method Development and Validation for the Estimation of Lansoprazole in Presence of Related Substances by QbD Approach

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Authors’ contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

A rapid specific RP-HPLC method has been developed for the determination of Lansoprazole impurities in the drug substance. The control of pharmaceutical impurities is currently a critical issue in the pharmaceutical industry. The International Council for Harmonization (ICH) has formulated a workable guideline regarding the control of impurities. The objective of the recent study was to develop and validate a HPLC method for the quantitative determination of process-related impurities of Lansoprazole in pharmaceutical drug substance. Lansoprazole, 2-[[3-methyl-4-((2,2,2-trifluoroethoxy)-2-pyridinyl)methyl]-sulfanyl]-1H-benzimidazole is a proton pump inhibitor used in the management of gastric ulcers. Chromatographic identification of the impurities was carried out by response surface methodology, applying a three-level Box Behnken design with three center points. Three factors selected were a mobile phase, flow rate, column temperature. Evaluation of the main factor, their interaction, and the quadric effect on peak resolution were done on Waters Symmetry C8, 250 x 4.6mm, 5µm column is used for the development of the method.
The mobile phase consists of buffer and acetonitrile. The flow rate of the mobile phase was 1.0 ml/min with gradient elution. The column temperature is ambient and the detection wavelength is 235 nm. The injection volume was 10 µL. The method was validated as per ICH guidelines for linearity in the range of 50-150 µg/ml and the LOD & LOQ values obtained were 0.437×10^{-6} and 0.1325×10^{-5} µg/ml respectively which specifies the method's sensitivity. The proposed method was successfully used to determine the Lansoprazole impurities in drug substances.

**Keywords:** Lansoprazole; RP-HPLC; impurities; linearity; validation; quality by design

1. **INTRODUCTION**

Lansoprazole, 

\[
2-\text{[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl] methyl-sulfinyl}-1H-benzimidazole, \]

which is an effective acid pump inhibitor acting at the acid secretory pathway of the parietal cell decreasing gastric acid secretion.[1] Clinically, it can be used for treatment of gastric ulcer, reflux esophagitis, duodenal ulcer, Zollinger-Ellison syndrome (gastrinoma), especially for the inhibition of Helicobacter pylori. Several analytical methods have been reported in the literature for the determination of Lansoprazole and its impurities.[2,3] Pharmaceutical impurities are unwanted chemicals that coexist with the active pharmaceutical ingredient (API) or develop during the formulation or ageing of both API and formulated APIs into medicines. Even small concentrations of these impurities can have an impact on a drug's effectiveness and safety. There are various types of sources of impurities that are affected by products.[4] That is synthesis related impurity, ii) organic impurity and, iii) inorganic impurity. The International Council for Harmonization (ICH) of technical requirements for registration of pharmaceuticals for human use ICH has also published guidelines for validation of methods for analyzing impurities in new drug substances, products, residual solvents, and microbiological impurities. In the overwhelming majority of the pharmacopeial monographs, impurities in the active pharmaceutical ingredient are determined by selective (usually high-performance liquid chromatography (HPLC)) or non-selective (usually titrimetric or ultraviolet (UV) spectrophotometry) methods.[5] HPLC is undoubtedly the most important method in drug-impurity profiling. It is widely used for separating and quantifying impurities, and this technique is most frequently used coupled with spectroscopic methods in the identifying and elucidating the structure of impurities.[6,7] Analytical method development and validation play important roles in drug discovery, Drug Development, and Manufacture of pharmaceuticals. It involves the detection of the purity and toxicity of a drug substance.

![Fig. 1. Structure of Lansoprazole](image1)

![Fig. 2. Structure of Chloro KSM Impurity](image2)

2. **MATERIALS AND METHODS**

2.1 **Equipment and Apparatus**

HPLC analysis was done by using a Shimadzu HPLC SILAD vp model chromatograph equipped with an LC20 AT gradient delivery system (pump), UV detector and column was Waters Symmetry C8, 250 x 4.6mm, 5µm. PC installed Chromeleon software was used to record and integrates the chromatograms. The analysis was carried out at ambient temperature. The UV detection was done using SHIMADZU UV visible spectrophotometer (double beam), and the wavelength range of 200 to 400 nm [8-10].

2.1.1 **Chemicals and materials**

Samples of Lansoprazole bulk material were obtained from the Research and Development Department, Dr. Reddy’s Laboratories Ltd., Hyderabad, India. The marketed preparations were purchased from the local market Brand Name ALTRADAY RANBAXY, Mumbai. HPLC
grade acetonitrile, methanol, TAF buffer was obtained from Merck (India) Limited.

2.1.2 Dilute acetic acid solution
Transfer 5ml of acetic acid into 100 ml volumetric flask containing 50 ml water and make up the volume with water and mix.

2.1.3 Preparation of 0.2N Sodium hydroxide solution
Dissolve 2.0 g of Sodium hydroxide pellets (NaOH) in 250 ml purified water and mix.

2.1.4 Preparation of Buffer solution
Transfer 7.71 g of ammonium acetate and 1m of triethylamine into a 2000 ml volumetric flask, mix and make the volume with water. Adjust the pH of this solution to 6.0 ± 0.05 with dilute acetic acid.

2.1.5 Preparation of mobile phase
Measure separately 600 volumes of buffer and 400 volumes of acetonitrile (60:40, v/v) and mix. Filter and degas through 0.45-micrometer membrane filter under vacuum.

2.1.6 Preparation of standard stock solution
Accurately weigh about 50 mg of Lansoprazole working standard into a 100 ml volumetric flask. Add 20 ml of 0.2N sodium hydroxide solution and dilute to volume with diluent and mix. Transfer 10 ml of this solution with a pipette into a 25 ml volumetric flask. Dilute to volume with diluent and mix. This solution contains about 0.2 mg/ml of lansoprazole sodium. Filter the solution through 0.45 µm membrane filter and inject into HPLC system.

2.1.7 Preparation of Impurity solution
Accurately weigh about 5.0 mg of Chloro KSM impurity working standard into a 100 ml volumetric flask. Add 20 ml of 0.2N sodium hydroxide solution and dilute to volume with diluent and mix.

2.1.8 Preparation of Mix standard solution
Transfer 10 ml standard stock and 1 ml Choro KSM impurity into a 25 ml volumetric flask dilute to volume with diluent and mix.

2.1.9 Optimized chromatographic condition
The separation of lansoprazole and related impurity were achieved using optimized chromatographic conditions as mentioned in Table. 1.

2.2 Method Design

2.2.1 Screening method
The screening was done using Placket- Burman design using design expert software 11. Total 12 runs were obtained; the response for the design was resolution of the peaks of the Lansoprazole. Results were put in design to further optimize the method in Table no. 2 & 3.

2.2.2 Optimization
It was done by response surface methodology, applying a three-level Box Behnken design with three center points. Three factors selected were a mobile phase, flow rate, column temperature. Evaluation of the main factor, their interaction, and the quadric effect on peak resolution were done. Acetonitrile concentration 60% and wavelength were kept constant as their effect on the resolution was less significant.

Experiments were conducted by making injections of standard Lansoprazole solution and the average resolution was analyzed using Design Expert 11 software.

The application of multivariate regression analysis resulted in a fitted full quadrate model for the average responses for peaks USP resolution given by the following equation.

\[ Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_{11} X_1^2 + \beta_{22} X_2^2 + \beta_{33} X_3^2 + \beta_{12} X_1 X_2 + \beta_{13} X_1 X_3 + \beta_{23} X_2 X_3 \]

Where, Y is the response, \( \beta_0 \) is the arithmetic mean response. \( \beta_1 \), \( \beta_2 \), and \( \beta_3 \) are regression coefficients of the factor \( X_1 \), \( X_2 \) and \( X_3 \) respectively. \( \beta_{11} \), \( \beta_{22} \), and \( \beta_{33} \) are squared coefficients \( \beta_1 \), \( \beta_2 \), and \( \beta_3 \) are interaction coefficients.

2.3 Method Validation [11]
The method was validated according to ICH Q2(R1) guidelines and obeyed all validation parameters.
2.3.1 System suitability

Test the system suitability performed by injecting blank solution once and spiked solution for six times into a HPLC system. The system suitability was established by evaluating the system suitability parameters from the chromatograms thus obtained. Typical system suitability parameters include %RSD, Tailing factor (T) and Theoretical plates (N) [12-18].

Table 1. Optimized chromatographic conditions

| Parameter          | Condition                        |
|--------------------|----------------------------------|
| Column             | Waters Symmetry C8, 250 x 4.6mm, 5µm |
| Mobile phase       | Buffer: Acetonitrile (60:40)     |
| Diluent            | Methanol: water: diethylamine (800:200:1) |
| Flow rate          | 1.0ml/min                        |
| Column temperature | Ambient                          |
| Injection volume   | 10µL                             |
| Run time           | 15 minutes                       |
| Detector           | UV-detector                      |
| Detection wavelength| 235nm                           |
| Elution            | Gradient                         |

Table 2. Chromatographic factors and response variables for Plackett-Burman experimental design

| Sr. No. | Parameters | Levels used |
|---------|------------|-------------|
|         |            | Low | Center | High |
| 1       | Flow rate  | 0.6 | 1.0    | 1.4  |
| 2       | Wavelength | 225 | 235    | 245  |
| 3       | Column     | 28  | 30     | 32   |
| 4       | Mobile phase (buffer %) | 49  | 50     | 51   |
| 5       | Inj. Volume| 8   | 10     | 12   |

Table 3. Plackett Burman method used for Lansoprazole

| LANSOPRAZOLE        | Run          | A:Flow Rate | B:Detection Wavelength | C:Column Temp | D:Mobile Phase | E:INJ Volume | Resolution |
|---------------------|--------------|-------------|-------------------------|---------------|----------------|--------------|------------|
|                     | Factor 1     | Factor 2    | Factor 3                | Factor 4      | Factor 5       | Response 1   |            |
|                     | ml/min       | nm          | °C                      | %             | µL             |              |            |
| 1                   | 1.4          | 245         | 28                      | 30            | 8              | 1.26         |
| 2                   | 0.6          | 245         | 32                      | 30            | 12             | 1.09         |
| 3                   | 0.6          | 245         | 32                      | 50            | 8              | 1.26         |
| 4                   | 1.4          | 225         | 32                      | 50            | 8              | 0.99         |
| 5                   | 1.4          | 225         | 32                      | 50            | 12             | 1.04         |
| 6                   | 1.4          | 245         | 28                      | 50            | 12             | 1.02         |
| 7                   | 0.6          | 225         | 32                      | 30            | 12             | 1.08         |
| 8                   | 1.4          | 225         | 28                      | 30            | 12             | 1.11         |
| 9                   | 0.6          | 225         | 28                      | 50            | 8              | 1.23         |
| 10                  | 0.6          | 245         | 28                      | 50            | 12             | 1.03         |
| 11                  | 1.4          | 245         | 32                      | 30            | 8              | 1.34         |
| 12                  | 0.6          | 225         | 28                      | 30            | 8              | 1.25         |
Table 4. Chromatographic factors and response variables for box-Behnken experimental design

| Sr. no. | Parameters            | Levels used |         |         |
|---------|-----------------------|-------------|---------|---------|
|         |                       | Low        | Center  | High    |
| 1       | Inj. volume           | 8          | 10      | 12      |
| 2       | Mobile phase          | 30         | 40      | 50      |
| 3       | Detection wavelength  | 225        | 235     | 245     |

Table 5. Box-Behnken method used for Lansoprazole determination optimization

| Run   | A: INJ Volume (µL) | B: Mobile Phase (%) | C: Detection Wavelength (nm) | Response 1 Resolution |
|-------|--------------------|---------------------|-----------------------------|------------------------|
| 1     | 10                 | 50                  | 225                         | 1.04                   |
| 2     | 10                 | 40                  | 235                         | 1.15                   |
| 3     | 8                  | 40                  | 245                         | 1.24                   |
| 4     | 10                 | 40                  | 235                         | 1.2                    |
| 5     | 8                  | 30                  | 235                         | 1.26                   |
| 6     | 8                  | 40                  | 225                         | 0.96                   |
| 7     | 12                 | 50                  | 235                         | 1.14                   |
| 8     | 10                 | 40                  | 235                         | 1.14                   |
| 9     | 10                 | 50                  | 245                         | 1.18                   |
| 10    | 12                 | 40                  | 225                         | 1.12                   |
| 11    | 8                  | 50                  | 235                         | 1.16                   |
| 12    | 10                 | 30                  | 245                         | 1.17                   |
| 13    | 10                 | 40                  | 235                         | 1.21                   |
| 14    | 10                 | 40                  | 235                         | 1.21                   |
| 15    | 12                 | 30                  | 235                         | 1.26                   |
| 16    | 10                 | 30                  | 225                         | 1.16                   |
| 17    | 12                 | 40                  | 245                         | 1.14                   |

2.3.2 Linearity

The linearity of the method was demonstrated over the range of 50-150%. The solutions at five levels of concentrations were prepared and 10µl of each of the solutions were injected into the HPLC system to obtain the chromatograms. The linearity curve was constructed by plotting average peak areas against concentration and the regression equation was calculated by the method of least squares. The correlation coefficient, y-intercept and slope of the regression line were reported.

2.3.4 Accuracy

The accuracy of the method was established by performing recovery studies. Recovery studies were performed by spiking sample solution with the pure authenticated standard drug at three different concentration levels i.e. 50, 100, 150% and LOQ solutions each in triplicate. The mean recovery of the five different concentrations of the drug was calculated.

2.3.5 Precision

The standard stock solution and impurity solutions were prepared and the concentration injected in triplicate into the HPLC system to obtain the chromatograms and the peak areas were recorded from the obtained peaks. Then average and the standard deviation of three peak areas at each concentration level were calculated.

Finally %RSD can be calculated by applying the formula

\[
\%RSD = \frac{100 \times SD}{X}
\]

Where,

SD = Standard deviation of 'n' responses,
X = mean of 'n' responses

2.3.6 LOD & LOQ

The LOD and LOQ of Lansoprazole by the proposed methods were determined using calibration standards. LOD and LOQ values were
calculated as $3.3 \sigma_S$ and $10 \sigma_S$, respectively, where $S$ is the slope of the calibration curve and $\sigma$ is the standard deviation of y-intercept.

3. RESULT AND DISCUSSION

3.1 Optimized Chromatographic Conditions

The separation of lansoprazole and related impurity were achieved using Buffer: Acetonitrile as mobile phase in the ratio of 60:40 at a flow rate of 1.0 ml/min with a gradient elution method. Detection and purity establishment of the main drug and impurity were achieved using photo diode array (PDA) detector at 235 nm with an injection volume of 10 µL and column temperature is ambient. The run time optimized was found to be 15 min.

3.2 Method Design

3.2.1 Plackett-Burman design

The screening was done by using Plackett-Burman design, which gives Pareto chart (Fig. 4) and Probability values (p-values) for flow rate, wavelength detection, column temperature, mobile phase, and injection volume [19-25].

![Chromatogram of method development of Lansoprazole](image_url)

**Fig. 3. Chromatogram of method development of Lansoprazole**

![Pareto Chart](image_url)

**Fig. 4. Pareto Chart Ranking of Lansoprazole**

Multivariate regression analysis was implemented then fitted with a full quadratic model which was obtained for the USP resolution factor of the peak. Here factors considered are injection volume, flow rate, and column temperature. The regression coefficient and p-values obtained from the software-generated report are given in (Table 6).

To obtain the optimum set of conditions to achieve the desired goal composite desirability parameters were applied. Optimum conditions
Table 6. Regression coefficients and associated probability values (p-values) for USP resolution of Lansoprazole

| Source               | Sum of Squares | df | Mean Square | F       | p-value | Prob > F |
|----------------------|----------------|----|-------------|---------|---------|----------|
| Model                | 0.080971471    | 9  | 0.008997    | 6.42303 | 0.01137 | significant |
| A-Inj volume         | 0.0002         | 1  | 0.0002      | 0.142784| 0.716726|           |
| B-Mobile phase       | 0.0136125      | 1  | 0.013613    | 9.718256| 0.016905|           |
| C-Detection wavelength | 0.0253125    | 1  | 0.025313    | 18.07114| 0.003788|           |
| AB                   | 0.0001         | 1  | 0.0001      | 0.071392| 0.797021|           |
| AC                   | 0.0169         | 1  | 0.0169      | 12.06527| 0.010357|           |
| BC                   | 0.004225       | 1  | 0.004225    | 3.016318| 0.126004|           |
| A^2                  | 2.63158E-07    | 1  | 2.63E-07    | 0.000188| 0.989446|           |
| B^2                  | 0.002179211    | 1  | 0.002179    | 1.555785| 0.252394|           |
| C^2                  | 0.019042368    | 1  | 0.019042    | 13.59476| 0.007786|           |
| Residual             | 0.009805       | 7  | 0.001401    |         |         |          |
Fig. 5. Response plot showing effects of injection volume and mobile phase on USP Resolution factor of Lansoprazole

Fig. 6. Response plot (3D) showing effects of injection volume and mobile phase on USP resolution factor of Lansoprazole

Fig. 7. Response plot (3D) showing effects of injection volume and detection wavelength on USP resolution factor of Lansoprazole
Fig. 8. Response plot (3D) showing effects of mobile phase and detection wavelength on USP resolution factor of Lansoprazole

Fig. 9. Chromatogram of optimized batch

having desirability were chosen from the obtained runs i.e. Flow rate 1 ml/min, Mobile phase TFA buffer: acetonitrile, Column temperature 27°C±2°C. A set of conditions were analyzed to compare the predicted response with the actual response.

3.3 Method Validation

RP-HPLC method developed was validated according to International Council for Harmonization (ICH) guidelines for validation of analytical procedures.

3.3.1 System suitability

System suitability studies were carried out in which the % RSD, tailing factor, member of theoretical plates found, were calculated. The resulting chromatograms exhibited a retention time of 16.165 min. From the system suitability studies, it was observed that 0.54% RSD of theoretical plates was to be more than 2000 and the tailing factor was found to be less than 2.

All the parameters were within the limits and the system suitability test was passed. % RSD for six replicate injections of peak area response for
standard spiked solution was found to be less than 2%, tailing factor was found to be less than 1.5 and number of theoretical plates was found to be more than 2000. All the system suitability parameters were satisfied, and thus the system suitability test was passed.

3.3.2 Linearity

The linearity of the drug was established by constructing the calibration curve with a concentration on the x-axis and peak area on the y-axis. From the calibration curve, it was observed that the method was linear over the concentration range of 50 – 150 (µg/ml) for Lansoprazole spiked solution and correlation coefficient ($r^2$) was found to be 0.9996.

3.3.3 Accuracy

The accuracy of the method was determined by performing recovery studies at 50%, 100%, 150%. The mean recovery of pure drug from the analyzed solution of the formulation was found to be in the accurate range. Hence, the method is said to be accurate.

3.3.4 Precision

Precision was determined by preparing the impurities mixed solution and injecting twice a day for 3 days. The %RSD of peak areas of chromatograms of impurities mixed lansoprazole was found to be less than 2%. Thus, the method passes the precision test.

Table 7. System suitability results for Lansoprazole

| Sr.no. | Retention Time (min) | Peak area | Resolution | USP Tailing Factor | USP Plate count |
|--------|----------------------|-----------|------------|-------------------|-----------------|
| 1      | 16.148               | 10620     | 7.19       | 1.16              | 98194           |
| 2      | 16.163               | 10644     | 7.17       | 1.22              | 97927           |
| 3      | 16.159               | 10648     | 7.07       | 1.15              | 100987          |
| 4      | 16.168               | 10701     | 7.21       | 1.16              | 99795           |
| 5      | 16.169               | 10677     | 7.23       | 1.08              | 100387          |
| 6      | 16.168               | 10786     | 7.26       | 1.09              | 99616           |
| Mean   | 16.162               | 10679.3   | 7.22       | 1.16              |                 |
| Standard deviation | 0.008     | 59.4      |            |                   |                 |
| %RSD   | 0.05                 | 0.6       |            |                   |                 |

Fig.10. Calibration curve of Lansoprazole
Table 8. Percent Recovery studied for accuracy of Lansoprazole

| Sr.no. | Sample Name          | Retention Time(min) | Recovery (%) | Mean  | Std. Dev. | % RSD  |
|-------|----------------------|--------------------|--------------|-------|----------|--------|
| 1     | Accuracy at 50% Prep-1 | 16.342             | 99.75        | 99.62 | 0.5804   | 0.58   |
| 2     | Accuracy at 50% Prep-2 | 16.328             | 98.99        |       |          |        |
| 3     | Accuracy at 50% Prep-3 | 16.322             | 100.13       |       |          |        |
| 4     | Accuracy at 100% prep-1 | 16.327             | 99.63        | 99.24 | 0.3711   | 0.34   |
| 5     | Accuracy at 100% prep-2 | 16.341             | 98.89        |       |          |        |
| 6     | Accuracy at 100% prep-3 | 16.362             | 99.21        |       |          |        |
| 7     | Accuracy at 150% prep-1 | 16.327             | 100.73       | 99.53 | 1.0733   | 1.08   |
| 8     | Accuracy at 150% prep-2 | 16.341             | 99.23        |       |          |        |
| 9     | Accuracy at 150% prep-3 | 16.362             | 98.65        |       |          |        |

3.3.5 LOD & LOQ

The limit of detection for Lansoprazole was found to be $0.437 \times 10^{-4}$ µg/ml. The LOD is the smallest concentration of the analyte that can be accurately quantified. The limit of quantitation for Lansoprazole calcium was found to be $0.1325 \times 10^{-3}$ µg/ml.

Table 9. Accuracy at LOQ of Lansoprazole

| Sr.No. | Sample Name | Retention Time(min) | Area       | USP Resolution | USP Tailing | USP Plate count |
|--------|-------------|---------------------|------------|----------------|-------------|-----------------|
| 1      | Accuracy at LOQ | 16.168              | 8616219    | 6.76           | 0.95        | 97354           |
| 2      | Accuracy at LOQ | 16.171              | 8621104    | 6.62           | 0.95        | 98302           |
| 3      | Accuracy at LOQ | 16.171              | 8645631    | 6.63           | 0.95        | 99193           |
| Mean   |             | 16.170              | 8627651.3  | 6.63           | 0.95        |                 |
| Std dev|             | 0.0.2               | 15760.9    |               |             |                 |
| %RSD   |             | 0.01                | 0.2        |               |             |                 |

Table 10. Precision Results of Lansoprazole

| Sr.No. | Retention Time(min) | Area       | USP Resolution | USP Tailing | USP Plate count |
|--------|---------------------|------------|----------------|-------------|-----------------|
| 1      | 16.183              | 8175667    | 6.75           | 0.95        | 95274           |
| 2      | 16.185              | 8142016    | 6.86           | 0.95        | 96315           |
| 3      | 16.186              | 8323887    | 6.80           | 0.95        | 98079           |
| 4      | 16.180              | 8156190    | 6.76           | 0.95        | 100259          |
| 5      | 16.184              | 8273392    | 6.78           | 0.95        | 95434           |
| 6      | 16.194              | 8244127    | 6.65           | 0.95        | 98162           |
| Mean   | 16.185              | 8219213.1  | 6.66           | 0.95        |                 |
| Std dev| 0.005               | 72581.5    |               |             |                 |
| %RSD   | 0.03                | 0.9        |               |             |                 |

4. CONCLUSION

There is no validated method available in the official pharmacopoeias like IP, BP, USP for the identification of Lansoprazole drug substance impurities with less retention time, accuracy and sensitivity, so attempts were made to develop a method by which the impurities present in the drug can be identified. In the proposed RP-HPLC method, the parameters were optimized to obtain suitable conditions for the analysis of Lansoprazole. The method with buffer and acetonitrile as the mobile phase at a flow rate of 1ml/min was found to be optimum. The optimum wavelength for detection was 235 nm at which a better detector response for Lansoprazole was obtained. The retention time was found to be 16.165 min. To ascertain the effectiveness the calibration was linear in the concentration range of 50 to 150 µg/ml with a correlation coefficient 0.999. No interference was seen due to mobile phase solvents (blank) and the impurities at the retention times of Lansoprazole confirm that the method was specific. The limits of detection and limit of quantitation for Lansoprazole were found...
to be $0.437 \times 10^{-4}$ and $0.1325 \times 10^{-3}$ respectively which specify the method's sensitivity.

The values of % RSD below 2% indicate that the method was precise. The method was found robust as the %RSD was below 2%. The theoretical plates were found to be 99742 and the tailing factor was found to be less than 2%. The proposed method was validated following ICH parameters. Finally, it can be concluded that the proposed method was found to be accurate, precise, sensitive and less retention time than previous methods and can be successfully applied for the identification of impurities related to Lansoprazole.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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