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# DETERMINATION OF ESOMEPRAZOLE IN PHARMACEUTICAL DOSAGE FORM USING UV AND RP HPLC METHOD

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**ABSTRACT**
This study presents the development and validation of analytical methods for the quantitative estimation of Esomeprazole, the S-enantiomer of omeprazole and a potent proton pump inhibitor (PPI) widely used in the management of acid-related gastrointestinal disorders including GERD, peptic ulcer disease, and Zollinger–Ellison syndrome. Two complementary analytical techniques – UV spectrophotometry and RP-HPLC – were developed and validated in accordance with ICH guidelines. The UV method involved measuring the absorbance of Esomeprazole at 305 nm using methanol as solvent. The method demonstrated excellent linearity within the concentration range of 2–12 µg/mL, with a correlation coefficient ($r^2$) of 0.9961. The RP-HPLC method was optimized using a mobile phase of 0.1% Triethylamine: Methanol (70:30, v/v), with detection at 250 nm on a C18 column (250 × 4.6 mm, 5 µm) at a flow rate of 1.0 mL/min, yielding a retention time of approximately 4.13 minutes. The HPLC method demonstrated linearity over the concentration range of 32–48 µg/mL (80–120%), with a correlation coefficient ($r^2$) of 0.9998. Validation parameters including precision, accuracy, LOD, LOQ, specificity, repeatability, and robustness confirmed the suitability of both methods. Both analytical methods were found to be simple, precise, accurate, economical, and reproducible, confirming their applicability for routine quality control of Esomeprazole in pharmaceutical dosage forms.

**KEYWORDS:** Esomeprazole, RP-HPLC, UV , Method Validation, ICH Guidelines, Pharmaceutical Analysis, chemistry.

## INTRODUCTION

Esomeprazole is the S-enantiomer of omeprazole, classified within the benzimidazole group of compounds. Its chemical designation is (S)-5-methoxy-2-[(4-methoxy-3,5-dimethylpyridin-2-yl)methylsulfinyl]-1H-benzimidazole with a molecular formula of $C_{17}H_{19}N_3O_3S$ and molecular weight of 345.42 g/mol [1]. The drug functions by specifically and irreversibly inhibiting the $H^+/K^+$-ATPase enzyme system (the gastric proton pump) found on the membrane of gastric parietal cells, thereby suppressing gastric acid secretion regardless of physiological stimuli [2].Gastrointestinal disorders including gastroesophageal reflux disease (GERD), peptic ulcer, and Zollinger–Ellison syndrome rank among the most prevalent acid-related conditions globally. Esomeprazole has acquired considerable clinical significance owing to its enhanced pharmacokinetic and pharmacodynamic profile compared to the racemic predecessor omeprazole. The single S-isomer formulation was designed to minimize inter-individual variability in metabolism primarily mediated by CYP2C19 and CYP3A4, resulting in more stable plasma concentrations and predictable acid suppression [3,4].Chemically, Esomeprazole is a white to slightly off-white crystalline powder with a melting point of 155–157°C. It is freely soluble in methanol, soluble in dichloromethane, but slightly soluble in water. Its acid-labile nature leads to degradation under acidic conditions forming inactive sulfenic acid and sulfone derivatives, making formulation into oral dosage forms particularly challenging [5].The analytical assessment of Esomeprazole tablets is a crucial component of formulation development, ensuring quality, stability, and efficacy. UV-Visible spectrophotometry and High-Performance Liquid Chromatography (HPLC) are the most commonly used techniques. HPLC, in particular, is the gold standard for determining purity, potency, and degradation products [6,7]. A review of existing literature indicates various UV methods with λmax values reported between 299–352 nm [8–14], and RP-HPLC methods validated using C18 columns with different mobile phase systems [15–20]. The present study aims to develop and validate simple, precise, accurate, and economical analytical methods using both UV spectrophotometry and RP-HPLC for quantitative estimation of Esomeprazole in pharmaceutical dosage forms in accordance with ICH guidelines.

## MATERIALS AND METHODS

### Estimation of Esomeprazole by UV Method

Solubility studies were conducted using various solvents including water, sodium hydroxide solution, and ethanol. Esomeprazole exhibited adequate solubility only in methanol, which was therefore selected as the solvent for UV spectral analysis. A standard stock solution of 1000 µg/mL was prepared by dissolving an accurately weighed quantity of Esomeprazole in methanol. For the determination of λmax, a 10 µg/mL standard solution was scanned between 200–400

nm using a Shimadzu UV-visible spectrophotometer against methanol as blank. Maximum absorbance (λmax) was observed at 305 nm. The linearity was established across a concentration range of 2–12 µg/mL. For the sample assay, 20 marketed tablets (Esomeprazole 40 mg) were weighed and powdered; an accurately weighed quantity of powder equivalent to the label claim was dissolved in methanol and absorbance was measured at 305 nm [21].

**Method Validation Parameters of UV**

Linearity was established across 2–12 µg/mL by plotting absorbance versus concentration. Limit of Detection (LOD) and Limit of Quantification (LOQ) were determined using signal-to-noise ratios of 3:1 and 10:1 respectively. Precision was evaluated as interday precision on three consecutive days and intraday precision by triplicate measurements on the same day using a 6 µg/mL standard solution. Accuracy was assessed at 50%, 100%, and 150% concentration levels by measuring absorbance at 305 nm and calculating percentage recovery. Robustness was evaluated by deliberately varying the wavelength by ±2 nm and assessing the impact on absorbance values.

**Estimation of Esomeprazole by HPLC Method**

Chromatographic analysis was performed using a Shimadzu LC-20AD HPLC system equipped with a DAD detector and Lab Solutions software. Four mobile phase trials were conducted to optimize separation. The final optimized conditions employed a mobile phase of 0.1% Triethylamine: Methanol (70:30 v/v), pH adjusted to 7.0 with dilute o-phosphoric acid, on a C18 column (Agilent Zorbax Bonus RP, 250 × 4.6 mm, 5 µm) at a flow rate of 1.0 mL/min, with detection at 250 nm, injection volume of 10 µL, run time of 15 minutes, and column temperature of 30°C. The standard stock solution (1000 µg/mL) was prepared by dissolving 4 mg of Esomeprazole working standard in 10 mL of diluent. Working standard solution (40 µg/mL) was prepared by further dilution. For sample preparation, ten tablets (40 mg Esomeprazole) were accurately weighed, crushed, and a quantity of powder equivalent to 4 mg of drug was dissolved in 10 mL of diluent and sonicated for 5 minutes, followed by further dilution to obtain 40 µg/mL.

**Method Validation Parameters of HPLC**

Linearity was assessed at five concentration levels in the 80–120% range (32–48 µg/mL). Specificity was evaluated by comparing the chromatographic profiles of blank, working standard, and drug product. Repeatability was determined by six consecutive injections of the standard (100% level). Intraday and interday precision studies were performed at 40 µg/mL. Robustness was evaluated by varying column temperature (±2°C) and detection wavelength (±2 nm). LOD and LOQ were calculated using the formula: $LOD = 3.3\sigma/S$ and $LOQ = 10\sigma/S$, where σ is the standard deviation of the response and S is the slope of the calibration curve. Recovery and accuracy were determined at 80%, 100%, and 120% of the nominal concentration [22,23].

**Optimized Chromatographic Conditions**

The chromatographic optimization involved four systematic mobile phase trials. Trial 1 (0.1% Triethylamine: Methanol, 50:50) yielded a broad peak; Trial 2 (45:55) showed a hump with low resolution; Trial 3 (40:60) also displayed low resolution. The final optimized condition with 70:30 (v/v) ratio produced a sharp, well-resolved, symmetrical peak with a retention time of approximately 4.13 minutes. System suitability parameters are presented in Table 1.

**Table 1: System Suitability Parameters of Optimized RP-HPLC Method**

| S.No | Parameter | Result |
|---|---|---|
| 1 | Column | C18 (5 µm particle size, 4.6 x 250 mm) |
| 2 | Mobile phase | 0.1% Triethylamine: Methanol (70:30) |
| 3 | Flow rate | 1.0 mL/min |
| 4 | Run time | 15 min |
| 5 | Wavelength | 250 nm |
| 6 | Detector | DAD detector |

## RESULTS AND DISCUSSION

### Method Validation of Esomeprazole by UV Method

#### Determination of λmax

The λmax of Esomeprazole was determined at 305 nm using methanol as solvent by scanning from 200–400 nm. This wavelength was selected for all subsequent UV analyses due to the distinct absorption maximum observed at this wavelength.

#### Linearity

Esomeprazole demonstrated linear absorbance response in the concentration range of 2–12 µg/mL with a correlation coefficient ($r^2$) of 0.9961, confirming Beer-Lambert compliance. The calibration equation was Y = 0.1016x + 0.0074. Linearity data are presented in Table 2.

**Table 2: Linearity of Esomeprazole by UV Method**

| Concentration (µg/mL) | Absorbance |
|---|---|
| 2 | 0.106 |
| 4 | 0.218 |
| 6 | 0.299 |
| 8 | 0.432 |
| 10 | 0.504 |
| 12 | 0.619 |
| Correlation coefficient ($r^2$) | 0.9961 |

**Precision**

Interday precision was evaluated over three consecutive days at 6 µg/mL. The %RSD values for Days 1, 2, and 3 were 0.504%, 0.828%, and 0.503%, respectively (Table 3), all well below 1%, indicating high precision. Intraday %RSD was 0.827% (Table 4), also within acceptable limits.

**Table 3: Interday Precision of Esomeprazole by UV Method**

| S.No | Absorbance | Mean | Standard Deviation | %RSD |
|---|---|---|---|---|
| Day-1 | 0.302, 0.303, 0.305 | 0.303 | 0.002 | 0.504 |
| Day-2 | 0.302, 0.307, 0.304 | 0.304 | 0.003 | 0.828 |
| Day-3 | 0.302, 0.305, 0.304 | 0.304 | 0.002 | 0.503 |

**Table 4: Intraday Precision of Esomeprazole by UV Method**

| S.No | Conc (µg/mL) | Absorbance | Mean | %RSD |
|---|---|---|---|---|
| 1 | 6 | 0.302 | 0.304 | 0.827 |
| 2 | 6 | 0.307 | 0.304 | 0.827 |
| 3 | 6 | 0.304 | 0.304 | 0.827 |

**LOD and LOQ**

The LOD and LOQ for Esomeprazole by the proposed UV method were calculated to be 0.00505 µg/mL and 0.0153 µg/mL respectively, confirming the high sensitivity of the method for detection and quantification at very low concentrations.

**Assay**

The tablet assay yielded an absorbance of 0.312 with a percentage purity of 102%, within ICH-acceptable limits, confirming the suitability of the method for marketed formulation analysis. Assay results are presented in Table 5.

**Table 5: Assay of Esomeprazole by UV Method**

| S.No | Parameters | Conc (µg/mL) | Absorbance | % Purity |
|---|---|---|---|---|
| 1 | Assay (Esomeprazole Tablet) | 6 | 0.312 | 102% |

**Recovery and Accuracy**

Recovery studies conducted at 50%, 100%, and 150% concentration levels yielded percentage recoveries ranging from 99.60% to 101.10% (Table 6), with all values close to 100%, confirming the high accuracy and freedom from excipient interference of the UV method.

**Table 6: Recovery of Esomeprazole by UV Method**

| Level | Std (µg/mL) | Sample (µg/mL) | Absorbance | % Recovery |
|---|---|---|---|---|
| 50% | 8 | 10 | 0.394 | 100.00 |
| | 8 | 10 | 0.393 | 99.74 |
| | 8 | 10 | 0.397 | 100.76 |
| 100% | 9 | 10 | 0.414 | 100.00 |
| | 9 | 10 | 0.417 | 100.72 |
| | 9 | 10 | 0.415 | 100.24 |
| 150% | 10 | 10 | 0.505 | 101.10 |
| | 10 | 10 | 0.503 | 99.60 |
| | 10 | 10 | 0.507 | 100.40 |

**Robustness**

Robustness of the UV method was evaluated by deliberate variations of wavelength by ±2 nm (303 nm and 307 nm). Negligible changes in absorbance values were observed with %RSD values remaining well below 2% (Table 7), confirming the method's reliability against minor procedural fluctuations.

**Table 7: Robustness of Esomeprazole by UV Method (Wavelength Variation)**

| Concentration | (-) 303 nm | 305 nm | (+) 307 nm |
|---|---|---|---|
| 10 µg/mL | 0.502 | 0.537 | 0.511 |
| 10 µg/mL | 0.518 | 0.535 | 0.512 |
| 10 µg/mL | 0.519 | 0.539 | 0.513 |

**Table 8: Summary of Analytical Validation Parameters – UV Method**

| Parameters | Observation |
|---|---|
| Absorption maxima (nm) | 305 nm |
| Linearity range (µg/mL) | 2–12 |
| Standard regression equation | Y = 0.1016x + 0.0074 |
| Correlation coefficient ($R^2$) | 0.9961 |
| LOD (µg/mL) | 0.00505 |
| LOQ (µg/mL) | 0.0153 |

**Method Validation of Esomeprazole by HPLC Method**

**Linearity**

The HPLC method demonstrated excellent linearity across the 80–120% concentration range (32–48 µg/mL) with a regression coefficient ($r^2$) of 0.9998. The calibration equation was y = 25887x – 962.4. Peak areas at each concentration level are shown in Table 9, and the linearity graph confirmed a strong linear relationship.

**Table 9: Linearity of Esomeprazole by RP-HPLC Method**

| % Level | Concentration (µg/mL) | Peak Area |
|---|---|---|
| 80 | 32 | 826543 |
| 90 | 36 | 932221 |
| 100 | 40 | 1032370 |
| 110 | 44 | 1141941 |

| | | |
|---|---|---|
| 120 | 48 | 1239413 |
| Correlation coefficient ($r^2$) | 0.9998 | |

**LOD and LOQ**
The LOD and LOQ for Esomeprazole by the proposed RP-HPLC method were determined to be 1.22 µg/mL and 3.69 µg/mL, respectively, confirming adequate sensitivity for quantitative pharmaceutical analysis.

**Specificity**
Specificity was confirmed by comparing chromatograms of the blank, working standard (retention time 4.13 min, peak area 1032370), and drug product (retention time 4.14 min, peak area 1034945, assay 100.25%). The blank chromatogram showed no interfering peaks at the retention time of Esomeprazole, demonstrating method selectivity. Results are presented in Table 10.

**Table 10: Specificity of Esomeprazole by RP-HPLC Method**

| Sample ID | Retention Time | Peak Area | Assay (%) |
|---|---|---|---|
| Blank | – | – | – |
| ESP Working Std | 4.13 | 1032370 | – |
| ESP Drug Product | 4.14 | 1034945 | 100.25 |

**Repeatability**
Six consecutive injections of the standard at 100% level yielded peak areas with an average of 1032744, standard deviation of 1221.93, and %RSD of 0.12%, with consistent retention time of 4.13 min and peak purity of 1.00 throughout, confirming excellent system precision (Table 11).

**Table 11: Repeatability of Esomeprazole by RP-HPLC Method**

| Sample ID | Peak Area | Retention Time | Theoretical Plates | Asymmetry | Peak Purity |
|---|---|---|---|---|---|
| 100% Inj 1 | 1032370 | 4.13 | 6003 | 1.07 | 1.00 |
| 100% Inj 2 | 1031227 | 4.13 | 5984 | 1.03 | 1.00 |
| 100% Inj 3 | 1034581 | 4.13 | 5966 | 1.02 | 1.00 |
| 100% Inj 4 | 1033557 | 4.13 | 6017 | 1.05 | 1.00 |
| 100% Inj 5 | 1032954 | 4.13 | 6130 | 1.06 | 1.00 |
| 100% Inj 6 | 1031772 | 4.13 | 6028 | 1.01 | 1.00 |
| AVG | 1032744 | 4.13 | - | - | - |
| % RSD | 0.12 | 0.00 | - | - | - |

**Intraday and Interday Precision**
Intraday and interday precision studies at 40 µg/mL yielded %RSD values of 0.37% (morning) and 0.36% (Day 2) for assay, and 0.23% and 0.31% for retention time, all well within the ICH acceptance criterion of ≤2.0% (Table 12).

**Table 12: Intraday and Interday Precision of Esomeprazole by RP-HPLC Method**

| Condition | Sample ID | Retention Time | Peak Area | % Assay |
|---|---|---|---|---|
| Morning | WS | 4.13 | 1032370 | – |
| | DP | 4.14 | 1034945 | 100.25 |
| Evening | WS | 4.13 | 1031945 | – |
| | DP | 4.14 | 1029141 | 99.73 |

| | | | | |
|---|---|---|---|---|
| % RSD | | 0.23 | | 0.37 |
| Day 2 | WS | 4.13 | 1029944 | – |
| | DP | 4.14 | 1025476 | 99.57 |
| % RSD | | 0.31 | | 0.36 |

**Robustness**

Robustness was assessed by deliberate variations in column temperature (28°C and 32°C) and detection wavelength (248, 250, and 252 nm). The method produced consistently symmetrical peak shapes with minor variations in retention time (4.13–4.14 min) and %RSD values below 0.15% for all parameters (Table 13), confirming the reliability of the method under slight operational changes.

**Table 13: Robustness of Esomeprazole by RP-HPLC Method**

| Variation | Condition | Sample ID | Retention Time | Peak Area | % Assay |
|---|---|---|---|---|---|
| Column temp | 28°C | WS / DP | 4.13 / 4.14 | 1031445 / 1031946 | 100.05 |
| Column temp | 32°C | WS / DP | 4.13 / 4.14 | 1032370 / 1034945 | 100.25 |
| Wavelength | 248 nm | WS / DP | 4.13 / 4.14 | 1033412 / 1034914 | 100.15 |
| Wavelength | 250 nm | WS / DP | 4.13 / 4.14 | 1032370 / 1034945 | 100.25 |
| Wavelength | 252 nm | WS / DP | 4.13 / 4.14 | 1034201 / 1035214 | 100.10 |
| % RSD | | | 0.13 | 0.12 | 0.09 |

**Assay**

The assay of the marketed tablet formulation yielded an Esomeprazole content of 39.96 mg (label claim: 40 mg), corresponding to 99.9% purity (Table 14), within pharmacopoeial acceptance limits and confirming the applicability of the developed HPLC method for routine quality control of commercial formulations.

**Table 14: Assay of Esomeprazole by RP-HPLC Method**

| S.No | Sample (tablet) | Label Claim | Conc (µg/mL) | Amount Present | % Purity |
|---|---|---|---|---|---|
| 1 | Esomeprazole | 40 mg | 40 | 39.96 mg | 99.9% |

**Recovery and Accuracy**

Recovery studies at 80%, 100%, and 120% of target concentration showed average % recoveries of 99.99%, 100.00%, and 99.64%, respectively (Table 15). All values were within the ICH acceptance range (98–102%), confirming the high accuracy and reliability of the RP-HPLC method across different concentration levels.

**Table 15: Recovery and Accuracy of Esomeprazole by RP-HPLC Method**

| Level | Injection | Spiked Conc (µg/mL) | Area | Amount Recovered (µg/mL) | % Recovery | AVG |
|---|---|---|---|---|---|---|
| 80% | Inj 1 | 31.97 | 826543 | 31.98 | 100.04 | 99.99 |
| | Inj 2 | 31.97 | 825438 | 31.94 | 99.91 | |
| | Inj 3 | 31.97 | 826344 | 31.97 | 100.02 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 100% | Inj 1 | 39.96 | 1032370 | 39.95 | 99.96 | 100.00 |
| | Inj 2 | 39.96 | 1031227 | 39.90 | 99.85 | |
| | Inj 3 | 39.96 | 1034581 | 40.03 | 100.18 | |
| 120% | Inj 1 | 47.95 | 1239413 | 47.96 | 100.01 | 99.64 |
| | Inj 2 | 47.95 | 1234645 | 47.77 | 99.63 | |
| | Inj 3 | 47.95 | 1230575 | 47.61 | 99.30 | |

**DISCUSSION**

The present study was undertaken to develop and validate simple, precise, accurate, economical, and reproducible analytical methods for the estimation of Esomeprazole in pharmaceutical dosage forms using UV spectrophotometric and RP-HPLC techniques, in accordance with ICH guidelines.In the UV spectrophotometric method, methanol was selected as the optimal solvent based on solubility studies. The drug showed maximum absorbance (λmax) at 305 nm, consistent with previously reported values [8,9]. The method obeyed Beer-Lambert's law across 2–12 µg/mL ($r^2$ = 0.9961). All precision studies demonstrated %RSD well below 1%, confirming high repeatability and reliability. Calculated LOD (0.00505 µg/mL) and LOQ (0.0153 µg/mL) values confirmed adequate analytical sensitivity. Recovery studies at three concentration levels yielded results close to 100%, confirming freedom from excipient interference. Robustness against wavelength variation of ±2 nm was confirmed with negligible changes in absorbance.For RP-HPLC, systematic optimization of the mobile phase composition through four chromatographic trials led to the selection of 0.1% Triethylamine: Methanol (70:30 v/v) as the optimized system. This composition produced a sharp, symmetrical peak for Esomeprazole with a retention time of 4.13 minutes on a C18 column, satisfying all system suitability requirements including theoretical plates >5900 and tailing factor <1.1. Excellent linearity ($r^2$ = 0.9998) across 32–48 µg/mL, repeatability (%RSD 0.12%), and precision (%RSD <0.4%) confirmed the method's robustness. Specificity was confirmed by the absence of interfering peaks in blank chromatograms. Robustness studies demonstrated that minor variations in temperature and wavelength did not significantly affect chromatographic performance. The assay result of 99.9% purity and recovery values between 99.64–100.00% validate the method's accuracy and suitability for pharmaceutical quality control. Both methods proved superior in their respective domains. The RP-HPLC method offers greater sensitivity, specificity, and precision, making it particularly suited for regulatory quality control and stability studies. The UV method, by contrast, provides a simpler, faster, and more cost-effective alternative for routine laboratory analysis. Both methods are complementary and together provide a comprehensive analytical toolkit for Esomeprazole quality assurance.

**CONCLUSION**

The study successfully developed and validated UV spectrophotometric and RP-HPLC methods for the quantitative estimation of Esomeprazole in pharmaceutical dosage forms. Both methods were validated as per ICH guidelines and demonstrated acceptable linearity, precision, accuracy, specificity, and robustness. The UV spectrophotometric method with λmax at 305 nm (linearity 2–12 µg/mL, $r^2$ = 0.9961) provides a simple, rapid, and economical tool suitable for routine quality control. The RP-HPLC method with optimized mobile phase 0.1% Triethylamine: Methanol (70:30 v/v) on a C18 column at 250 nm (linearity 32–48 µg/mL, $r^2$ = 0.9998) exhibited superior sensitivity and specificity. Both validated methods are reliable, reproducible, and applicable for routine quality control and research analysis of Esomeprazole in pharmaceutical industries and laboratories.

**LIMITATIONS OF THE STUDY:**

The study did not evaluate forced degradation behavior or impurity profiling, limiting confirmation of stability-indicating performance. Method validation was confined to tablet formulations without assessment in biological matrices. Analysis was restricted to a single marketed product formulation, which may limit broader applicability across different commercial brands.

**FUTURE STUDY:**

Future studies should incorporate forced-degradation and stability-indicating method development along with impurity profiling. Validation in biological matrices (plasma/urine) would broaden clinical applicability. Evaluation of multiple commercial brands and application of advanced techniques such as UHPLC or LC–MS/MS may further improve selectivity and analytical performance.

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**AUTHORS CONTRIBUTION:**

Dr. Sheela Rani T designed the experimental framework, supervised the study, Mahesh kumar contributed to data interpretation. Akshaya K performed the experimental work, data acquisition, and drafted the manuscript.

**CONFLICT OF INTEREST:**
The authors declare that there is no conflict of interest.

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Not applicable.

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**ABBREVIATIONS:**
UV – Ultraviolet spectrophotometry
RP-HPLC – Reverse Phase High Performance Liquid Chromatography
HPLC – High Performance Liquid Chromatography
LOD – Limit of Detection
LOQ – Limit of Quantification
SD – Standard Deviation
RSD – Relative Standard Deviation
RT – Retention Time
ICH – International Conference on Harmonisation
GERD – Gastroesophageal Reflux Disease
PPI – Proton Pump Inhibitor
DAD – Diode Array Detector
λmax – Wavelength of Maximum Absorbance
TEA – Triethylamine
WS – Working Standard
DP – Drug Product

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