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RP-HPLC method development of Linezolid tablet in Pharmaceutical Dosage Form

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Abstract

A synthetic antibiotic of the oxazolidinone class called linezolid is used to treat infections brought on by bacteria that are resistant to many antibiotics, such as methicillin-resistant Staphylococcus aureus and streptococcus (MRSA). HPLC method was developed for linezoid tablets. The developed technique was found to be fast, sensitive and precise, and possess potential to separate the drug yet as all the most important and minor degradation product, that proves its stability indicating nature.

Key words: Method development, Reversed phase HPLC method, Tablet dosage forms,

Introduction

The medications chosen for the proposed study include Linezolid mesylate, which has been investigated in biological fluids using several incredibly effective liquid chromatography (HPLC) techniques. A few publications on methods for determining the drug's stability high-performance thin layer chromatography and HPLC are available (HPTLC). Several papers on stability propose HPLC, high-performance thin layer chromatography (HPTLC), and thin layer chromatography as assessment techniques for linezolid, according to a literature search for the drug (TLC). The drug's metabolite identification and characterization investigations were also reported on. The drug's pharmacokinetics, toxicology, and identifying and classifying process-related impurities were also investigated1. The present study was aimed to develop RP-HPLC method for the linezolid tablets.

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Material and Method

HPLC method validation[2-5]

The created technique was examined for parameters like linearity, precision, accuracy, specificity and selectivity.

Linearity

The linearity was established by utilising concentrations between 50 and 300 g mL-1 in a stock solution that contained 1 mg mL-1 of the medication. By injecting 20 L into HPLC, the solutions were made in triplicate and examined.

Precision

By evaluating 100 g mL-1, 200 g mL-1, and 300 g mL-1 drug solutions three times on the same day and the following day, respectively, the intra-day and inter-day precision was established. The values of the relative standard deviation were computed.

Accuracy

The accuracy was assessed by triplicate injections of three known drug concentrations, namely 100 g mL-1, 200 g mL-1, and 300 g mL-1, into a mixture of stressed samples. The recovery of the additional medication was then calculated.

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Specificity and selectivity

Peak purity utilizing a PDA detector was determined to establish the method's specificity. To demonstrate that the devised approach was selective in nature, peak purity and resolution were really determined for all the DP peaks in addition to the drug peak.

Results and Discussion

In terms of linearity, precision, accuracy, specificity, and selectivity, the devised method was validated.

Linearity

In table the linearity data are displayed, and Fig. displays the relevant linearity plot. The drug's reaction was discovered to be linear in the study's range of10-60µgmL [1]

Table 1: Linearity data for linezolid tablets

Conc. (µgmL^{-1})	Average area	±SD	RSD (%)	Slope	Correlation Coefficient (r^1)
10	811130.86	4801.41	0.68		
10	1410883.80	18101.43	1.10		
30	1138161.01	10815.80	0.88	805681	0.8888
40	1861881.66	16085.48	0.81		
50	3533631.81	18163.03	0.88		
60	4138108.88	30355.85	0.81		

Key: SD–Standarddeviation,RSD–Relativestandarddeviation

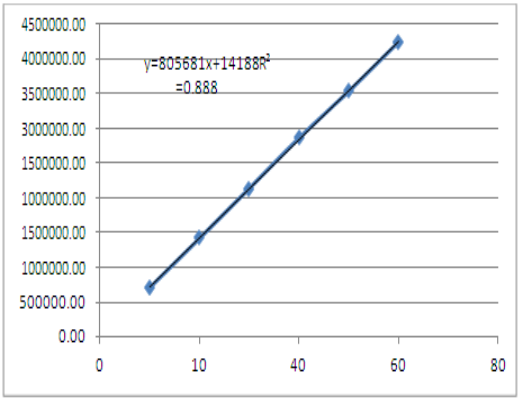

Fig. 1 Calibration plot of linezolid tablets

Precision

The findings from three distinct intra- and inter-day precision studies Table displays concentrations (10 g mL-1, 40 g mL-1, and 60 g mL-1) for each. The method's %RSD values for intra-day and inter-day precision were less than 1%, indicating that it was accurate enough.

Table 2: Precision for linezolid tablets

	Intra-day precision	Inter-day precision
Conc. (µgmL^{-1})	Measured conc., ±SD (µgmL^{-1}), RSD(%)	Measured conc., ±SD (µgmL^{-1}), RSD(%)
10	10.13 ± 0.168, 1.34	10.18 ± 0.156, 1.18
40	38.68 ± 0.188, 0.80	38.80 ± 0.464, 1.16
60	60.06 ± 0.388, 0.63	60.11 ± 0.486, 0.81

Accuracy

When accuracy was evaluated by spiking a combination of stressed samples with the three known doses of the medication, namely 10 g mL-1, 40 g mL-1, and 60 g mL-1, the percent recovery ranged between 88.10% and 101.30%. Table displays the accuracy data.

Table 2: Accuracy for linezolid tablets

Spiked conc. (µgmL^{-1})	Calculated spiked conc.(µgmL^{-1}), ±SD (µgmL^{-1}), RSD(%)	Recovery (%)
10	18.61, ± 0.408, 0.34	88.10
40	40.51, ± 0.881, 0.58	101.30
60	58.03, ± 0.851, 0.53	88.38

Specificity

Peak purity data acquired using a PDA detector demonstrated that the approach was particular to each peak. Table 6.14 displays the retention time, relative retention time, and peak purity statistics for the medication and degradation products.

Drug/degradation products	Retention time	Relative retention time	Peak purity index
DP-I	8.80	0.61	0.888841
DP-II	10.86	0.88	0.888868
DP-III	11.00	0.85	0.888866
Drug	14.04	1.00	0.888888

Conclusion

The developed technique was found to be fast, sensitive and precise, and possess potential to separate the drug yet as all the most important and minor degradation product, that proves its stability indicating nature.

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