INTRODUCTION
Faropenem is chemically 6-(1-hydroxyethyl)-2-[(2R)-tetrahydrofuran-2-yl]-2,3-didehydropenam -3-carboxylic acid. Faropenem is a novel β-lactam antimicrobial agent sharing structural similarities with both the penicillins and cephalosporins. It exhibits a broad spectrum of activity that includes Gram-negative, Gram-positive and some anaerobic bacteria. The primary mode of action of faropenem is consistent with that of other β-lactam antibiotics, namely binding to penicillin-binding proteins. Faropenem has been shown to demonstrate high stability to a number of β-lactamases, including TEM-1, SHV-1 to -5, TEM-3 to -9 and the β-lactamase produced by Staphylococcus aureus. Literature survey revealed that only a few analytical methods such as high performance liquid chromatography (HPLC) method have been reported. Hence, a new sensitive and efficient HPLC method was developed and validated for the assay of the drug in tablets. The structure of Faropenem is shown in Figure 1.

MATERIALS AND METHODS
A Waters HPLC system consisting of a Water 2695 binary gradient pump, an inbuilt auto sampler, a column oven and Water 2487 dual wavelength absorbance detector (DAD) was employed throughout the analysis. The data was acquired using Empower 2 software. The column used Symmetry C18 (4.6 x 150mm, 5 μm, Make: ODS) or equivalent A Bandline sonerex sonicator was used for enhancing dissolution of the compounds. An Adwa digital pH meter was used for pH adjustment. Analytically pure Faropenem was obtained as gift samples from Hetro drugs Ltd., Hyderabad, India. Acetonitrile, methanol, water (E. Merck, Mumbai, India) were of HPLC grade, while ortho-phosphoric acid and potassium dihydrogen phosphate (S. D. Fine Chemicals, Mumbai, India) were of Analytical grade used for the preparation of mobile phase.

Preparation of mobile phase and stock solutions
Potassium dihydrogen phosphate was weighed (2.72 g) and dissolved in 1000 ml of water. Finally the pH was adjusted to 4.0 with ortho phosphoric acid. The solution was sonicated for 5 minutes and filtered using Whatman filter paper. For the estimation of Faropenem from the tablets, twenty tablets Average weight was calculated and their contents were mixed thoroughly. The powder equivalent to 10mg was weighed accurately and transferred into a 10ml volumetric flask, dissolved and dilute up to mark with diluent. Mix well and filter through 0.45μm filter.

Chromatographic conditions
A reverse phase C18 column equilibrated with mobile phase phosphate buffer-Acetonitrile in the ratio (70:30%v/v) pH adjusted to 4.0 with ortho phosphoric acid was used. Mobile phase flow rate was maintained at 0.9 mL/min and eluents was monitored at 317 nm. The sample was injected using a 20 μL fixed loop, and the total run time was 5 min.

Determination of Faropenem dosage form
For the estimation of Faropenem from the tablets, twenty tablets were taken and their contents were mixed thoroughly. Average weight was calculated. Tablet content or the powder equivalent to 10mg was weighed accurately and transferred into a 10ml volumetric flask, dissolved and dilute up to mark with diluent. Take above solution 0.8 ml in 10 ml volumetric flask dilute up to mark with diluent (80ppm). Mix well and filter through 0.45μm filter. The solution was injected at above chromatographic conditions and peak areas were measured. The quantification was carried out by keeping these values to the straight line equation of calibration curve. The method was validated for accuracy, precision, specificity, detection limit, quantitation limit and robustness.

Accuracy
The accuracy of the method was determined by calculating recovery of Faropenem by the normal method. Known amount of Faropenem was added to a pre quantified sample...
solution, and the amount of Faropenem was estimated by measuring the peak areas and by fitting these values to the straight-line equation of calibration curve.

**Precision**
The intraday and interday precision study of Faropenem was carried out by estimating the corresponding responses 5 times on the same day and on different days. The results are reported in terms of relative standard deviation. The repeatability studies were carried out by estimating response of 5 different concentrations of Faropenem and results are reported in terms of relative standard deviation (%RSD)

**Specificity**
Commonly used excipients were spiked into a pre weighed quantity of drugs. The chromatogram was taken by appropriate dilutions and the quantities of drugs were determined.

**Detection limit and quantitation limit**
Baseline noise obtained from blank injection is 46 μV. Signal to Noise ratio for the determination of detection limit for Faropenem is 2.95 and quantitation limit is 10.3.

**Robustness**
Robustness of the method was studied by change in Organic Composition in the Mobile Phase ± % 10 and the flow rate 1.0 and 0.8 ml/min instead of 0.9 ml/min.

![Figure 1: Structure of Faropenem](image1)

![Figure 2: HPLC chromatogram of Faropenem in optimized chromatographic conditions](image2)

![Figure 3: Linearity curve for Faropenem](image3)

**Table 1: Validation parameters and data for proposed method**

<table>
<thead>
<tr>
<th>Validation parameter of Faropenem</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linearity</td>
<td>40-120 μg/mL</td>
</tr>
<tr>
<td>Regression coefficient (r²)</td>
<td>0.999</td>
</tr>
<tr>
<td>Limit of detection (μg/mL)</td>
<td>0.03</td>
</tr>
<tr>
<td>Limit of quantitation (μg/mL)</td>
<td>0.12</td>
</tr>
<tr>
<td>*Accuracy (% recovery)</td>
<td>100.1%</td>
</tr>
<tr>
<td>**Precision (%RSD)</td>
<td>0.06</td>
</tr>
<tr>
<td>***Intermediate precision (%RSD)</td>
<td>0.11</td>
</tr>
<tr>
<td>Assay value (%)</td>
<td>99.3</td>
</tr>
<tr>
<td>System suitability parameter</td>
<td></td>
</tr>
<tr>
<td>Tailing factor</td>
<td>1.2</td>
</tr>
<tr>
<td>Number of theoretical plates</td>
<td>2883.0</td>
</tr>
</tbody>
</table>

* Replicates of three concentration levels (in three determinations); ** Five repetitive injections of same homogeneous sample
RESULTS AND DISCUSSION
Optimization of mobile phase was performed based on asymmetric factor and peak area obtained for Faropenem. The mobile phase phosphate buffer- Acetonitrile in the ratio (70:30%v/v) adjusted to pH 4.0 using ortho phosphoric acid was found to be satisfactory and gave symmetric peak for Faropenem the retention time for Faropenem was 3.05 min respectively (Figure 2).

The calibration curve for Faropenem was obtained by plotting the peak area of Faropenem versus the concentration of Faropenem over the range of 40-120 µg/ml, and it was found to be linear with $r^2 = 0.999$. The detection limit for Faropenem was 0.03µg/ml respectively. The quantitation limit for Faropenem was 0.12µg/ml respectively, which suggests that a nanogram quantity of the compound can be estimated accurately. The validation parameters are summarized in (Table 1). The recovery Faropenem was found to be 100.1% respectively. The system suitability test parameters are shown in (Table 1). The liquid chromatographic method was applied to the determination of Faropenem in dosage form. The results for Faropenem were comparable with the corresponding labeled amount.

CONCLUSION
Proposed study describes a new RP-HPLC method for the estimation of Faropenem using simple mobile phase with low buffer concentration compared to the reported method. The method gives short analysis time (<5 min). The method was validated and found to be simple, sensitive, accurate and precise. Percentage of recovery shows that the method is free from interference of the excipients used in the formulation. Therefore, the proposed method can be used for routine analysis of Faropenem in dosage form.

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REFERENCES

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