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# NEW RP-HPLC METHOD FOR THE SIMULTANEOUS ESTIMATION OF MEROPENEM AND VABORBACTAM IN PHARMACEUTICAL DOSAGE FORM

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## ABSTRACT

A new precise, accurate, rapid method has been developed for the simultaneous estimation of MPN and VBB in pharmaceutical dosage form by RP-HPLC.The optimum wavelength for the determination of MPN and VBB was selected at 254 nm on the basis of isobestic point. Various trials were performed with different mobile phases in different ratios, but finallyAmmonium Phosphate Buffer pH 5.0: Acetonitrile(75:25) %v/v) was selected as good peak symmetry and resolution between the peaks was observed.The Retention time of MPN and VBBwere found to be 2.829&3.862 min respectively. The Retention times for both the drugs were considerably less compared to the Retention time obtained for the drugs in the other mobile phase. The different analytical performance parameters such as linearity, precision, accuracy, and specificity were determined according to International Conference on Harmonization ICH Q2B guidelines. The calibration curve was obtained by plotting peak area versus the concentration over the range of 50-150 µg/mL For MPN and50-150 µg/mL forNLT. From linearity the correlation coefficient $R^2$ value was found to be 0.9991for FTF and 0.9997 for NLT. The proposed HPLC method was also validated for system suitability, system precision and method precision. The %RSD in the peak area of drug was found to be less than 2%. The number of theoretical plates was found to be more than 2000, which indicates efficient performance of the column. The percentage of recovery of MPN and VBBwere found to be 99.8 and 100.4respectivelyshows that the proposed method is highly accurate.

**Key Words:** Meropenem, Vaborbactam, pharmaceutical dosage form.

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## INTRODUCTION

HPLC was derived from classical column chromatography and has found an important place in analytical techniques. It's a physical separation technique in which a sample dissolved in a liquid is injected into a column packed with small particles and it is separated into its constituent components. It is probably the most important and widely used analytical technique for quantitative analysis of organics and biomolecules, also applicable to much kind of samples. HPLC utilizes a liquid mobile phase to separate the components of a mixture. The stationary phase can be a liquid or a solid phase. These components are first dissolved in a solvent, and then forced to flow through a chromatographic column under a high pressure. In the column, the mixture separates into its components. The amount of resolution is important, and is dependent upon the extent of interaction between the solute components

and the stationary phase. The stationary phase is defined as the immobile packing material in the column. The interaction of the solute with mobile and stationary phases can bemanipulated through different choices of both solvents and stationary phases. As a result, HPLC acquires a high degree of versatility not found in other chromatographic systems and it has the ability to easily separate a wide variety of chemical mixtures [1-3]. Meropenem is a broad-spectrum carbapenem antibiotic. It is active against Gram-positive and Gram-negative bacteria. Meropenem exerts its action by penetrating bacterial cells readily and interfering with the synthesis of vital cell wall components, which leads to cell death.In August 2017, a combination antibacterial therapy under the market name vabomere was approved for treatment of adult patients with complicated urinary tract infections (cUTI). Vabomere consists of meropenem and Vaborbactam and is intravenously admininstered. The treatment aims to resolve infection-related symptoms and achieve negative urine culture, where the infections are proven or strongly suspected to be caused by susceptible bacteria.Vaborbactam is a β-lactamase inhibitor based on a cyclic boronic acid pharmacophore. It has been used in trials investigating the treatment of bacterial infections in subjects with varying degrees of renal insufficiency. In August 2017, a combination antibacterial therapy under the market name Vabomere was approved by the FDA for the treatment of adult patients with complicated urinary tract infections (cUTI) [4, 5].Aim is to develop new RP-HPLC method for the simultaneous estimation of Meropenem and Vaborbactam _in pharmaceutical dosage form.

## MATERIALS AND METHODS

### Preparation of Standard solution [6-8]

About 100 mg of MPN and100mg of VBB were weighed into a 100 mL volumetric flask, to this 70mL of mobile phase was added, sonicated and the volume was made up with the mobile phase.Pipetted 5 mL of the clear solution in to 50 mL volumetric flask and make up volume with mobile phase.

### Preparation of Sample solution

Weigh quantity of powder equivalent to100mg of MPN and100mg of VBBin100 mL volumetric flask and add70mL of mobile phase then sonicated it for 30minintermittent shacking after 30min make up volume with mobile phase. Pipetted 5 mL of the clear solution in to 50 mL volumetric flask and make up volume with mobile phase.Filter the solution through 0.45µm filter paper.

## RESULTS AND DISCUSSION

The %RSD of 6 determinations of MPN and VBB for System precision found to be within the acceptance criteria of less than 2.0% (Table-1).

**Table-1 Method precision results for MPN and VBB**

| Injection | MPN | | VBB | |
|---|---|---|---|---|
| | Area | %Assay | Area | %Assay |
| 1 | 1026668 | 100.0 | 2029924 | 100.4 |
| 2 | 1032616 | 100.5 | 2018744 | 99.8 |
| 3 | 1025772 | 99.9 | 2030331 | 100.4 |
| 4 | 1017071 | 99.0 | 1995114 | 98.6 |
| 5 | 1016907 | 99.0 | 2018534 | 99.8 |
| 6 | 1011321 | 98.5 | 2013040 | 99.5 |
| Average | - | 99.5 | - | 99.7 |
| SD | - | 0.8 | - | 0.6 |
| %RSD | - | 0.8 | - | 0.6 |

A graph was plotted for MPNand VBBagainst the concentrations of the solutions and the peak areas (Table-2 and 3). The correlation coefficient $R^2$ was determined and was found to be 0.999 for ATE (Fig-1) and 0.999 for VBB (Fig-2).

**Table-2 Linearity data of MPN**

| S.No | Concentration (µg/mL) | Area |
|---|---|---|
| 1 | 50 | 558053 |
| 2 | 80 | 813525 |
| 3 | 100 | 1016907 |
| 4 | 120 | 1200288 |
| 5 | 150 | 1455360 |

**Table-3 Linearity data of VBB**

| S.No | Concentration (µg/mL) | Area |
|---|---|---|
| 1 | 50 | 999261 |
| 2 | 80 | 1634827 |
| 3 | 100 | 2018534 |
| 4 | 120 | 2422240 |
| 5 | 150 | 3067801 |

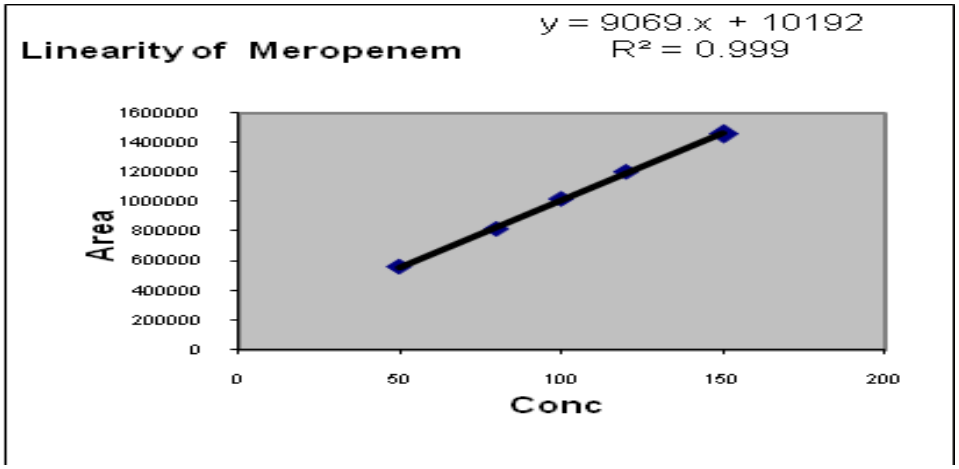


**Fig-1 Graph for Linearity data of MPN**

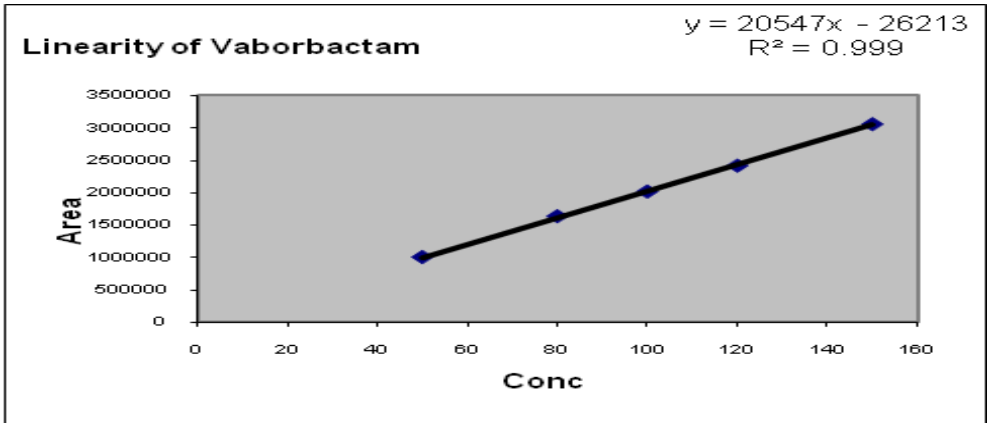


**Fig-2 Graph for Linearity data of VBB**

The % mean recovery of MPN and VBBwas found between 98.0 to 102.0 (Table-4 and 5)

**Table-4 Results for Recovery of MPN**

| %Recovery | Amount present (µg/mL) | Amount found (µg/mL)* | Percent Recovery * | % Mean Recovery |
|---|---|---|---|---|
| 50% | 50 | 49.64 | 99.3 | 99.2 |
| 100% | 100 | 99.17 | 99.2 | |
| 150% | 150 | 148.63 | 99.1 | |

**Table-5 Results for Recovery of VBB**

| %Recovery | Amount present (µg/mL) | Amount found (µg/mL)* | Percent Recovery * | % Mean Recovery |
|---|---|---|---|---|
| 50% | 50 | 49.86 | 99.7 | 100.4 |
| 100% | 100 | 99.98 | 100.0 | |
| 150% | 150 | 152.08 | 101.4 | |

## CONCLUSION

The proposed method is highly sensitive, precise and accurate and it successfully applied for the quantification of API content in the commercial formulations of MPN and VBBin Educational institutions and Quality control laboratories.

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