INTERNATIONAL CONFERENCE

10th International Pharmaceutical Conference „Science and Practice 2019”

ABSTRACT BOOK

November 15th, 2019

Kaunas, Lithuania

Development of the method for determination of metoprolol in human plasma

Liliya Logoyda[1]*, Mariana Horyn[1], Sergiy Kovalenko[2]

[1]Pharmaceutical Chemistry Department, Pharmaceutical faculty, I. Horbachevsky Ternopil State Medical University, Ternopil City, Ukraine
[2]Organic and Bioorganic Chemistry Department, Zaporizhzhya State Medical University, Zaporizhzhya City, Ukraine
**Corresponding author e-mail: logojda@tdmu.edu.ua*

Introduction: The method development process can be broken down into components with a logical progression. In practice, the process is more a series of iterative and interlinked steps that may often need to be revisited and adjusted to finally arrive at the best method. The present study was aimed to develop a rapid, specific and sensitive method based on LC-MS/MS method was developed for the determination of metoprolol.
Materials and methods: Chromatography was achieved on Discovery C18, 50 × 2.1 mm, 5 µm column. Samples were chromatographed in a gradient mode (eluent A (acetonitrile – water – formic acid, 5 : 95 : 0.1 v/v), eluent B (acetonitrile – formic acid, 100 : 0.1 v/v)). The initial content of the eluent B of 8%, which increases linearly to 1.0 min to 100%, is maintained up to 1.5 minutes and returned to the original 8% to 1.51 minutes. The mobile phase was delivered at a flow rate of 0.400 ml/min into the mass spectrometer ESI chamber. The sample volume was 4 µl [1-3].
Results: The total chromatographic run time was 2.0 minutes. A linear response function was established at 1 - 100 ng/ml for metoprolol and IS in human plasma. The % mean recovery for metoprolol in LQC, MQC and HQC was 104.1 %, 100.0 % and 97.4 %. The lowest concentration with the RSD <20% was taken as LLOQ and was found to be 1.03 ng/ml for metoprolol. The within-run coefficients of variation ranged between 0.271 % and 0.478 % for metoprolol. The within-run percentages of nominal concentrations ranged between 99.12 % and 100.21 % for metoprolol. The between-run coefficients of variation ranged between 0.388 % and 0.601 % for metoprolol. The between-run percentages of nominal concentrations ranged between 98.78 % and 101.11 % for metoprolol.
Conclusions: A highly sensitive, specific, reproducible, rapid and high-throughput LC-MS/MS assay was developed and validated to quantify metoprolol in human plasma as per the regulatory guidelines. Due to the sensitivity of the developed method, it can be applied to the monitoring of plasma levels in the analysis of drug in preclinical and clinical pharmacokinetic studies. All the parameters and results were found within the acceptance limit as given in the validation protocol.

References

1. Guideline on Bioanalytical method validation: European Medicines Agencies; 2011.
2. Sonawane LV, Poul BN, Usnale SV. Bioanalytical method validation and its pharmaceutical application a review. Pharm Anal Acta 2014;5:1-7.
3. Pushpa Latha E, Sailaja B. Bioanalytical method development and validation by HPLC: a review. J Appl Pharm 2014;1:1-9.