Pharmaceutical Sciences
March 2018, 24, 1-2
doi: 10.15171/PS.2018.01
http://journals.tbzmed.ac.ir/PHARM

Editorial

Analytical Method Validation: The Importance for Pharmaceutical Analysis

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Analytical methods play significant role in many branches such as, food production, natural product analysis, environmental analysis, pharmaceutical and biomedical analysis, and life sciences, etc. In order to reach reliable, accurate and repeatable data validated analytical methods need to achieve this aim.[1-3]

Validation is the key factor in controlling the reliability of a method that is determined by validation results, where specificity, accuracy, precision, limit of detection (LOD) and limit of quantification (LOQ), sensitivity and applicability are reported. Validated analytical methods play a major role in achieving the quality and safety of the final product especially in pharmaceutical industry. Analytical method validation should always be understood with respect to the life cycle of the analytical procedure.[4-9]

As a general statement, analytical methods performed in three basic steps:

- Identification of appropriate and necessary validation parameters,
- Design of experiments for parameter evaluation,
- Determination of acceptance criteria.

Method validation was firstly introduced in USA as a regulatory requirement in late 1978. The US Food and Drug Administration (FDA) issued a guideline in 1987 namely, *Guideline for Submitting Samples and Analytical Data for Methods Validation.*[1-3,10-14]

In addition to this document, there are some other guidelines, protocols and pharmacopeias in the literature. Among the FDA, some other useful protocols can be addressed in International Council on Harmonization (ICH), Current Good Manufacturing Practice (cGMP), United States Pharmacopeia (USP), Turkish Pharmacopeia, European Medicines Agency (EMA), International Organization for Standardization (ISO), Association of Analytical Chemists (AOAC), and the American Public Health Association.[3-5,10-13,15-20]

According to the above guidelines, validation is characterized by following parameters;

- Selectivity/Specificity
  - For raw material
  - For the investigated samples
- Linearity
- Range
- Limit of detection (LOD)
- Limit of quantification (LOQ)
- Accuracy
- Precision
  - Repeatability
  - Intermediate precision
  - Reproducibility
- Robustness
- Ruggedness
- Stability
- Applicability

Specificity, LOD, precision and stability should be investigated if the methods are qualitative while linearity and range, LOQ, accuracy and applicability of the method required as additional parameters in the quantitative methods.[1,2,6-9] Robustness and stability determined when they are desirable.[14]

Validation is a continuous process, and it should comprise at least four steps for an analytical following:

- Planning and performing of the tests
- Statistical evaluation of the results
- Report of the validation parameters
- Application of all information gained during full validation processes and their explanations.

While planning the test procedures, one has to take into account the statistical tests that are to be applied by software that allowed to perform statistical tests.

While the scope of the *Pharmaceutical Sciences* journal covers

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- Medicinal and Pharmaceutical Chemistry
- Pharmaceutics
- Pharmacognosy
- Pharmacology and Toxicology
- Pharmaceutical Biotechnology
- Pharmaceutical Nanotechnology
- Pharmacoeconomy
- Radiopharmacy

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- Water, Food, Drug and Cosmetic Control

The authors who would like to submit their precious studies to the journal should be validated their works in order to show the applicability and universality of their analytical methods.
For this reason, the authors may follow some review papers, book chapters, books, and guidelines for further reading that they can find in the references.[1-20]

Conflict of interests

The author claims that there is no conflict of interest.

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