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Application, principle and operation of ICP-OES in pharmaceutical analysis

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Abstract
Ensuring the quality of medicine is a global challenge. The demand for pure and safe medicines is increasing day by day. Thus, elemental impurities detection in pharmaceutical products is of great concern. New regulations for elemental impurities are now implemented by various authorities and included in guidelines. In recent years, inductively coupled plasma optical emission spectroscopy (ICP-OES) emerged as the best technique for quantification of impurities in pharmaceutical products. Many guidelines also have instructions for using ICP-OES in pharmaceutical analysis to measure the quality of the products. At the same time, it is playing a vital role in the determination of elements in human blood, urine and other biological fields. This article will focus on the application of ICP-OES along with the principle and operation to reveal its importance in the pharmaceutical industry.

Keywords: Elemental impurities, pharmaceutical analysis, ICP-OES

1. Introduction
Pharmaceutical science is a field of study that is related to dosage form(s), people and their physical safety. Two vital issues are necessary for drug therapy: safety and efficacy [1-3]. So, the determination of elemental impurities in the drug dosage form is highly essential to ensure quality and purity. The presence of impurities must be evaluated depending on the pharmacological and toxicological profiles. Impurities can be present in pharmaceutical products from the synthesis of raw materials to finished product manufacturing. These contaminants have no other therapeutic effects but their presence can provide toxic effects on the patient. The common impurities are cadmium, copper, chromium, mercury, iridium, molybdenum, nickel, osmium, lead, tungsten, palladium, platinum, rhodium, vanadium and so on. Currently, inductively coupled plasma optical emission spectroscopy (ICP-OES) is using as the most powerful technique in the pharmaceutical analysis due to its accuracy and sensitivity [4]. Also, it is beneficial for sample preparation because making multiple dilutions is eliminated as it can detect multiple elements from an analysis. Besides, it is using successfully in the analysis of DNA, protein, and trace of elements in the human body [5-6]. Thus, ICP-OES is now playing a significant role in the pharmaceutical industry and research area.

2. Materials and Methods
2.1 Source and effects of impurities
Detection and quantification of trace amount of impurities are highly recommended due to their adverse effect on the human body. Impurities can result from various sources in pharmaceutical products like: during synthesis, solvent, reagent, reaction vessel, equipment and so on. The low dose of heavy metal (e.g.: lead, cadmium, mercury) can cause serious physical damage. On the other hand, long-time exposure to heavy metal is also dangerous for our life. For example, daily exposure of 0.06 mg lead for one month can lead to kidney damage, demineralization and lung disorder. Thus, the presence of heavy metal is now strictly monitored and limited by regulatory authorities, like International Conference Harmonisation (ICH), Food and Drug Administration (FDA) and so on. Many authorities (United States Pharmacopeia, British Pharmacopoeia, European Pharmacopoeia and so on) are providing new specifications and testing procedures for inorganic based reagents or contaminates. As per European Pharmacopoeia (EP), the limit for platinum is 20 µg/g in Calcium Folinate. Thus, ICP-OES is widely using for regular analysis in the pharmaceutical industry [4-6].

2.2 Principle
ICP-OES has been commercially available since 1974 and detects elements for sample by using plasma (the fourth state of matters, next to solid, liquid & gas) and spectrometer. This instrument consists of a light source, detector, spectrometer and data processing unit. The basic principle is when plasma energy is provided to a sample from outside, the component elements are excited. Emission rays are released when the excited atoms return to low energy position and the emission rays that correspond to the photon wavelength are determined by the spectrometer. The element type is measured depending on the position of the photon rays, and the component of each element is determined based on the intensity of the rays.
Argon gas is supplied to the torch coil to generate plasma, and the high-frequency electric current is given to the work coil at the tip of the torch tube. The torch consists of quartz and three concentric tubes by which argon flows. Argon gas is ionized and plasma is produced by the electromagnetic field created in the torch tube through the high-frequency current. This plasma has a high electron density and temperature (6000K-10000K). In the torch desolvation, atomization and ionization of the sample happen and samples are given in an atomized state into the plasma by the narrow tube in the center of the torch tube [7-8].

2.3 Sample preparation and precaution
The sample should be acidified during the preparation of the sample for ICP-OES analysis due to keep metals in the solution. To make an acidic solution, nitric acid will be the best option as hydrochloric acid causes precipitation and sulfur from sulfuric acid can hamper the analysis. Samples must be delivered in 12 – 15 ml tubes. After completing the task, the user must remove any excess dust or particle remaining on the instrument by using a soft cotton cloth or tissue. Users should not use any organic solvents or abrasive materials for cleaning purposes. Users must not view ICP torch directly without any protective eyewear. During the analysis, the available argon pressure should be between 550 and 825 kPa (80-120 psig) and the shear flow is 25 L/min (1 cubic foot/min) at a minimum of 550 kPa (80 psig). The preferable laboratory temperature is between 15 and 30 °C (59-95 °F) with a maximum rate of change of 2.8 °C (5 °F) per hour during the operation of the instrument. The room temperature should be controlled at 20 ±2 °C; relative humidity should be between (20-80) % and non-condensing, for optimum instrument performance [7-8].

2.4 Drawback
This tremendous technique has a great advantage in the pharmaceutical and biomedical areas. It is not only used for metallic contaminant detection in pharma products but also used for human plasma, blood. It is used extensively in the proteomics field, which quantifies metals in the protein. Instead of these all wonderful benefits, this instrument has some flaws. Signal fluctuation is a crucial problem that leads to generating error results. Additionally, this technology doesn't have enough validated methods for impurities detection and calculation which is the most vital drawback. Thus, scientists should pay more attention and research for method validation [5-6].

3. Conclusions
ICP-OES is an excellent technique having accuracy and sensitivity to trace impurities present in medicine and biological products. More research and nourishment will make it one of the leading instruments in the pharmaceutical and biomedical sectors and more reliable for ensuring the health safety of patients.

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