26th Congress of SCTM



Sept. 20-23, 2023, Metropol Lake Resort, Ohrid, N. Macedonia

Determination of Trace Metals in Salbutamole Sulfate With ICP-OES

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The accurate determination of trace metals in pharmaceutical products is of great importance for their safety and efficacy. Salbutamol sulfate is a commonly used bronchodilator drug and it is often manufactured using palladium as a catalyst. However, trace amounts of it can remain in the final product, and this can have implications for patients sensitive to the metal. Therefore, determination of palladium content is of crucial importance when assessing the quality of the product.

In this study, inductively coupled plasma - optical emission spectroscopy (ICP-OES) was applied for data collection. The method was optimized by adjusting various parameters in order to be suitable for our instrument type: RF power 1.2 kW, reading time 5 s, stabilization time 25 s, viewing mode - axial, viewing height - 8 mm, nebulizer flow 0.7 L/min, plasma flow 12.0 L/min, aux flow 1.5 L/min, make up flow 0.00 L/min. Three replicates of each measurement were performed with pump speed 12 rpm, uptake delay 30 s and rinse time 35 s. Calibration was performed using five standards (0.08; 0.2; 0.4; 0.6 and 0.8 ppm) at wavelength 340.458 nm, and 1% HCl as blank solution (zero standard concentration).

Salbutamol sulfate is known to be highly hygroscopic drug and can absorb moisture from the atmosphere rapidly. The presence of moisture can cause the substance to decompose, which can generate heat, so the samples were first dissolved in a suitable solvent (1% HCl) and then injected into the instrument. The measured palladium content in the samples is expressed in ppm with correlation coefficient of 0.9997. The obtained result is 0.0019 ppm (limit - NMT 1 ppm).

Overall, this modified method is cost-effective and rapid and can be used successfully for quality control purposes, pharmacological and pharmaceutical research where Salbutamol sulfate palladium content determination is required.

Keywords: bronchodilator drug, catalyst, ICP-OES, ppm, hygroscopic

References

- 1. Merusomayajula, K. V., Tirukkovalluri, S. R., Kommula, R. S., Chakkirala, S. V., Vundavilli, J. K., Kottapalli, P. K. S. R. Development and validation of a simple and rapid ICP-OES method for quantification of elemental impurities in voriconazole drug substance. *Fut. J. Pharm. Sci.* **2021**, 7, 45 (2021); https://doi.org/10.1186/s43094-020-00159-2
- 2. Salbutamol: Uses, Dosage, Side Effects, Warnings Drugs.com
- 3. ICP-OES principle, ICP-OES Analysis, ICP-OES FAQ's | Agilent