

Evaluation of Elements Impurities in Drugs According to Pharmacopoeia by use FESEM-EDS Technique

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Abstract : Elemental Impurities in the Pharmaceuticals industry are indispensable to ensure pharmaceutical safety for 24 elements. Although atomic absorption and inductively coupled plasma are used in the U.S Pharmacopeia and the European Pharmacopoeia, FESEM with energy dispersive spectrometers can be applied as an alternative analysis method for quantitative and qualitative results for a variety of elements without chemical pretreatment, unlike other techniques. This technique characterizes by shortest time, with more less contamination, no reagent consumption, and generation of minimal residue or waste, as well as sample preparations time limiting, with minimal analysis error. Simple dilution for powder or direct analysis for liquid, we analyzed the usefulness of EDS method in testing with field emission scanning electron microscopy (FESEM, SUPRA 55 Carl Zeiss Germany) with an X-ray energy dispersion (XFlash6110 Bruker Germany). The samples analyzed directly without coating by applied 5µ of known concentrated diluted sample on carbon stub with accelerated voltage according to sample thickness, the result for this spot was in atomic percentage, and by Avogadro converted factor, the final result will be in microgram. Conclusion and recommendation: The conclusion of this study is application of FESEM-EDS in US pharmacopeia and ICH /Q3D guideline to reach a high-precision and accurate method in element impurities analysis of drugs or bulk materials to determine the permitted daily exposure PDE in liquid or solid specimens, and to obtain better results than other techniques, by the way it does not require complex methods or chemicals for digestion, which interfere with the final results with the possibility of to keep the sample at any time for re analysis. The recommendation is to use this technique in pharmacopeia as standard methods like inductively coupled plasma both ICP-AES, ICP-OES, and ICP-MS.

Keywords : pharmacopoeia, FESEM-EDS, element impurities, atomic concentration

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