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Elemental analysis and Heavy metals

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In accordance with the monographs of the European and US Pharmacopoeias (Ph. Eur.; USP), for reasons of patient safety, the heavy metals in pharmaceutical finished products and raw materials must not exceed the specified limit values and must be tested for that. Heavy metals can be introduced into the product by catalysts, synthesis reagents and even by the manufacturing process itself.

In the manufacturing of pharmaceutical products, catalysts containing heavy metals are often involved in the synthesis. Heavy metals can also transfer into the process by abrasion or by leaching (e.g. Fe, Ti, Cu, Cr and so on.) If they are not removed efficiently, then the tainted products could get into the market.

Legal regulations

For many years, it has been known that certain heavy metals exhibit toxic effects even at low concentrations.

As a result, limit values for the protection of the patients have been defined in the legislation and in the various pharmacopoeias (e.g. Ph. Eur., USP, JP, BP).

Detection methods

If testing is not performed for a specific heavy metal, the most common source of evidence nowadays come from a limit test being carried out. After treatment, the heavy metal is complexed with thioacetamide or precipitated as a sulphide. Then, one compares the resulting colouring of the sample solution against that from a reference lead solution.

These limit tests still form the majority of testing for heavy metals in the current national and international Pharmacopoeias (e.g. Ph. Eur. 2.4.8 or USP <231>). Thereby, it is possible however to make only a semiquantitative statement about the total contents of heavy metals in the sample, and in addition – and additionally, only for those heavy metals that actually form dark coloured complexes or sulphides.

Biography

Muhammad Jehangir has 14 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, Product development and Pharmaceutical manufacturing, Process Planning, Method development, Method validation, Statistical Methodology, Process & Cleaning Validation, and Equipment Validation etc. Certificate Courses on cGMP, cGLP, Process Validation, CTD Documents, ISO 17025:2017, ISO 9001:2008, 13485-2003, and 14001-2004 have strong scientific, analytical, statistical, managerial and training skills.

Currently he is working as a Senior Manager Quality Control and validation for Novamed Pharmaceuticals. It is toll manufacturing oriented company, manufacturing of companies like Getz Pharma, ICI, SEARLE, Macter, Ray, and for Sanofi-Aventis. He is also looking after the Quality of Novamed Healthcare, the nutraceutical and Cosmeceuticals manufacturing plant.

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