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Hyphenated Mass Spectrometric techniques: Revolution in Pharmaceutical Analysis

Somenath Ganguly
Sun Pharmaceutical Industries Ltd, India

In recent days hyphenated mass spectrometric techniques are becoming an essential tool in generic pharmaceutical analysis. United States and European pharmacopeia recommends methods in the general chapters and monographs. Techniques involve are LCMS/MS; GCMS; ICP MS; TGA MS etc. ICH; OSHA, EMEA , US FDA published guidelines for assessing genotoxic and elemental impurities in the active pharmaceutical ingredient(API) and finished drug products. Genotoxic impurities involves structures like Epoxides; Alkylating agents; Aldehydes; Nitro compounds; Hydrazines; Azo compounds etc. Elemental impurities arising out of the catalysts used in the API synthesis like palladium charcoal; nickel acetate, borohydrides; metal residues from reactors line like lead, arsenic, mercury and cadmium. The quantitation levels of these impurities are determined based on maximum daily intake of the drugs and in general limits are in the range of less than 50 ppm.Analytical methods need to be developed, adequately validated and transferred to QC locations as per ICH and regulatory requirements. Challenges and procedures in the analytical method development and validations process involving hyphenated mass spectrometric techniques will be discussed.

somenath.ganguly@sunpharma.com
somenathganguly15@gmail.com

Thermodynamic assessment of Cs-Te system

Pham Thi Tam Ngoc
University of Natural Ressource and Environnement, Vietnam

The operating conditions of mixed oxide fuels (MOX) in Sodium cooled Fast Reactor (SFR) are very severe combining high temperature, high linear rating and high temperature gradient. In the nominal operating conditions of a SFR, the linear power is around 2 kW/cm^3 and the temperature varies from 2500K down to 800K between the center and the periphery of the oxide fuel pellets. Due to those conditions, the volatile Fission Products (FP) like cesium and tellurium generated in the central region of the fuel pellet migrate outward through the radial cracks of the fuel matrix. At high burn up, a mixture of compounds of FP is formed in the fuel-cladding gap. This layer of FP compounds located between the external surface of the fuel pellet and the inner cladding surface is called in french the Joint Oxyde Gaine (JOG). The knowledge of phase equilibria and thermodynamic properties of the Cs–Te system is thus crucial for understanding and modeling the diffusion processes during the formation of the JOG. In this work, we present the review of phase diagram, crystallographic data and thermodynamic data of the Cs–Te binary system. The thermodynamic modeling of this system is also performed with the aid of the Thermo-Calc software. The thermodynamic descriptions derived in this work are based on the databases of Scientific Group Thermodata European (SGTE) and TBASE (ECN, Petten, Netherland) for the pure elements and the gaseous species. The compound formation and liquid mixing Gibbs energy ex- pressions are obtained by a least square optimization procedure. Comparisons between calculated and available experiments results are presented. A satisfactory agreement is achieved.

phamtamngoc@yahoo.fr