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Chemometrics in biosimilarity and stability assessment; Analytical review

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Statement of the Problem: Nowadays, biological is not a future dreams, biological is a fundamental part of healthcare worldwide with growing needs to safe, efficient, interchangeable and cost effective biosimilars. At this end, simple, accurate and reliable biopharmaceutical analysis is a great priority for both industry and regulatory authorities.

Aim: The aim of this work was to review, discuss and focus on statistically guided approaches used along with many analytical techniques for biosimilarity and stability assessment.

Methodology & Theoretical Orientation: Principal component analysis was the main unsupervised chemometric model to be highlighted. Other models coupled to different analytical techniques (NMR, HPLC-UV and HPLC-MS/MS) were also reviewed.

Findings: This coupling was found to be competent for detecting the similarities and dissimilarities between samples and also determining to what extent different samples are actually "different".

Conclusion & Significance: The mathematical modeling of big multivariate analytical data has given very informative and rewarding outcome that could be beneficial to National Control Laboratories especially in countries with price sensitive markets where the exhaustive assessment of imported biotechnological products including biosimilars is crucial. Recommendations are made for inclusion of chemometrics laboratory at each organization committed with research and control of biologics.

Recent Publications:

1. Sara M Shatat, Basma M Eltanany, Abeer A Mohamed, Medhat A Al-Ghobashy, Faten A Fathallaa and Samah S Abbas (2018) Coupling of on-column trypsin digestion–peptide mapping and principal component analysis for stability and biosimilarity assessment of recombinant human growth hormone. *Journal of Chromatography B* 1072:105-115.
2. Jawed Fareed, Peter Bacher and Walter Jeske (2018) Advances in heparins and related research: an epilogue. *Molecules* 23(2).
3. Kang Chen, Junyong Park, Feng Li, Sharadrao M Patil and David A Keire (2017) Chemometric methods to quantify 1D and 2D NMR spectral differences among similar protein therapeutics. *AAPS PharmSciTech* 19(3):1011-1019.
4. Boštjan Japelj, Gregor Ilc, Jaka Marušič, Jure Senčar, Drago Kuzman and Janez Plavec (2016) Biosimilar structural comparability assessment by NMR: from small proteins to monoclonal antibodies. *Scientific Reports* 6:32201

Biography

Basma M Eltanany is an Assistant Professor of Analytical Chemistry and Instrumental Analysis in the Faculty of Pharmacy at Cairo University, Egypt. She is a Postdoctoral Researcher at the same faculty. She has completed her BSc in Pharmaceutical Sciences and her MSc in Analytical Chemistry in 2006 and 2012, respectively and a PhD degree in Analytical Chemistry in 2016. She has published number of articles in referred journals and participated in national and international conferences. She was selected and awarded a scholarship for academic staff mobility (TEACHING AND TRAINING) at University of Porto, Portugal. Her current research interests include biosimilarity assessment, Chemometrics and separation sciences. Her interests also include development and validation of analytical and bioanalytical methods for determination of pharmaceutical compounds in different matrices.

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