Counterfeit Product Identification using Broadband Acoustic Resonance Dissolution Spectroscopy (BARDS)

Ní Chrónín,E.; Alfarsi, A.; MC Sweeney, S.; Keating, J.J and Fitzpatrick, D.
* Department of Chemistry, University College Cork, Ireland

Abstract:

The objective of this work is to demonstrate the potential of a new platform technology called BARDS to discriminate between genuine and counterfeit products, e.g., Cialis, Levitra and Viagra tablets. A simple dissolution test, taking <3 minutes, is shown to provide reproducible changes in the compressibility of the solvent which is unique to a particular tablet formulation. The changes in compressibility are measured through corresponding changes in acoustic resonant frequencies of the dissolution vessel. Counterfeit formulations are shown to produce significantly different acoustic profiles compared to genuine products.

Authentic and counterfeit tablets of the products were measured in duplicate as received using a BARDS spectrometer. A dissolution vessel containing 25 mL of 0.1M HCl was induced to resonate using a magnetic stir bar. Background resonances are observed for 30 seconds before the auto-addition from a tipper of a split tablet. The dissolution medium rapidly dissolves the half tablets which results in outgassing and reproducible changes in the compressibility of the solution which in turn alters the resonant frequencies of the vessel.[1-4] The method harnesses an acoustic effect reported notably by F.S. Crawford.[5]

Time vs frequency plots were obtained during the dissolution of the tablets using dedicated software. Genuine products are shown to yield reproducible and consistent data indicative of formulations produced under high specifications. However, counterfeit tablets produce different acoustic profiles which are less reproducible which indicates poor blend uniformity of the formulations. Different frequency minima in the spectra, as well as the time taken to return to steady state of the system are all indicators as to whether the material being tested is authentic pharmaceuticals or counterfeits when compared to the control of the genuine drug. Further work is required to produce a larger statistical dataset of counterfeit products (n=30).

Broadband Acoustic Resonance Dissolution Spectroscopy was shown to differentiate between genuine and counterfeit samples of three prescription drug products. This represents a rapid 'low tech' approach but with high tech implementation to screen suspect products using genuine product as a reference control.

References:

1. 1 Fitzpatrick, D., J. Krüse, et al. (2012). "**Principles and Applications of Broadband Acoustic Resonance Dissolution Spectroscopy (BARDS): A Sound Approach for the Analysis of Compounds.**" Analytical Chemistry 84(5): 2202-2210.
2. Fitzpatrick, D., R. Evans-Hurson, et al. (2013). "**The relationship between dissolution, gas oversaturation and outgassing of solutions determined by Broadband Acoustic Resonance Dissolution Spectroscopy (BARDS).**"Analyst 138(17): 5005-5010.
3. Fitzpatrick, D., E. Scanlon, et al. (2012). "**Blend uniformity analysis of pharmaceutical products by Broadband Acoustic Resonance Dissolution Spectroscopy (BARDS).**" International Journal of Pharmaceutics 438(1-2): 134-139.
4. Fitzpatrick, D., R. Evans-Hurson, et al. (2014). "**Rapid Profiling of Enteric Coated Drug Delivery Spheres via Broadband Acoustic Resonance Dissolution Spectroscopy (BARDS).**" Analyst 139(5): 1000-1106.
5. Crawford, F.S., (1981) '**The hot chocolate effect'** American Journal of Physics, 50(5), 398-404.

Email: Dr. Dara Fitzpatrick (**d.fitzpatrick@ucc.ie)**