Detection of Poor Acid Resistance of Enteric Coats using Surface Dissolution Imaging

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Abstract:

The acid resistance of an enteric coat is affected by both formulation and processing conditions. As part of a QbD approach to developing a tablet coat many formulation and processing parameters are investigated to understand which factors could be classed as a Critical Quality Attribute (CQA). Currently the acid resistance of the applied coat is determined by dissolution in a compendial dissolution apparatus with 0.1M Hydrochloric acid. Typically such methods require a prolonged running time (e.g. 2 hours) to understand the effect of prolonged exposure to acid and to establish a suitable solution concentration that can be measured. Also it is not possible to determine where the tablet defects are (i.e. the embossed region).

Surface dissolution imaging (SDI), using ultra-violet spectroscopy, has been shown to provide real-time information of the dissolution process at the surface of active ingredients and formulations. Using SDI it was possible to rapidly visually the release of the active ingredient from the tablet in 0.1M HCl. It was also possible to determine the region of the tablet where the defect was located. Such a test could result in a rapid method for testing the effects of different coating parameters/formulations on the coat quality.