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Pharmaceutical film coating catalogue for spectral-domain optical coherence tomography

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Abstract

Optical coherence tomography (OCT) has recently been demonstrated to measure the film coating thickness of pharmaceutical tablets and pellets directly. The results enable the analysis of inter- and intra-tablet coating variability at an off-line and in-line setting. To date, only a few coating formulations have been tried and there is very little information on the applicability of OCT to other coatings. As it is well documented that optical methods including OCT are prone to scattering leading to limited penetration, some pharmaceutical coatings may not be measurable altogether. This study presents OCT measurements of 22 different common coatings for the assessment of OCT applicability.

Keywords: optical coherence tomography; pharmaceutical film coating; coating thickness.

1. Introduction

Film coatings serve the very purpose of achieving colour uniformity, light protection, and taste masking. Coatings are additionally used to modify the drug release or to incorporate an active pharmaceutical ingredient in the formulation. Coating quality can be studied either by numerical modelling [1] or by the aid of process analysers. Various process analytical technology (PAT) approaches have been demonstrated for characterising pharmaceutical coating, which include NIR and Raman spectroscopy [2-4], nuclear magnetic resonance imaging [5], terahertz pulsed imaging (TPI) [6-8] and optical coherence tomography (OCT) [9-15]. Amongst these methods, TPI and OCT are attractive because they offer a direct, calibration-free coating thickness measurement, where the only unknown is the coating refractive index that can be obtained as a one-off measurement with terahertz time-domain spectroscopy and spectroscopic ellipsometry, respectively. Comparing the two, TPI has limited resolution (i.e., a lateral spatial of 200 μm and axial (depth) resolution of 2 μm for coating thickness greater than 30-40 μm) and requires relatively long measurement times (in the range of 8 ms). OCT in contrast, can achieve sub-μm resolutions for coating thickness greater than 10 μm and exploits an μs acquisition time leading to information on both inter-tablet and intra-tablet coating variation. Specifically, OCT has been demonstrated in an off-line [9-11] and in-line setting for characterising pellets [12, 13] and