Determination of moisture content in pharmaceutical pellets using near infrared spectroscopy: Method development and validation

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Concerning batch release in the pharmaceutical industry, the conformity analyses can be time consuming if all of them are performed after the manufacturing process. From this concept is born Process Analytical Technology (PAT) (1): it enables to monitor in real time each critical step of a manufacturing process reducing batch release time. Moreover, thanks to its real time character, PAT gives also the opportunity to tune manufacturing parameters in order to avoid the loss of potential batches. Pellets manufacturing process involves many steps such as blending, granulation, extrusion, spheronization and drying. A real time monitoring system like PAT is then particularly convenient to control such a complex process (2). Thanks to its non invasive, non destructive character and fast data acquisition, near infrared spectroscopy is more and more integrated in the PAT system, especially in the pharmaceutical field (2, 3). The aim of the present study was to develop and finally validate a near infrared model that was able to determine accurately a moisture content ranging from 1 to 8 % in pharmaceutical pellets

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