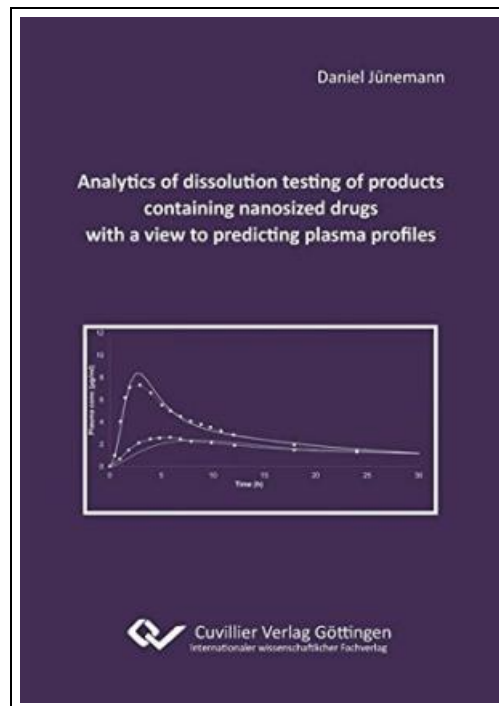


Analytics of dissolution testing of products containing nanosized drugs with a view to predicting plasma profiles



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
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Cuvillier Verlag Okt 2015, 2015. Taschenbuch. Condition: Neu. Neuware - The oral bioavailability of a drug substance is strongly related to its aqueous solubility. Only complete dissolution during the GI-passage can maintain an optimal bioavailability. Poor aqueous drug solubility results, according to the Nernst-Brunner equation into a slow dissolution rate, sometimes too slow for complete dissolution in the GI tract. The dissolution rate increases with decreasing particle size and therefore increasing surface area of the drug particles. In consequence, micronization of the drug is applied to increase oral bioavailability, but often meets with modest success. Recently developed techniques were applied to decrease the particle size into the nanometer range. For some substances, pharmacokinetic parameters could be influenced decisively, e.g. the obviation of a food effect for the drugs aprepitant and fenofibrate. The assessment of a dosage form is investigated by dissolution testing. For a reasonable assessment of such tests, a separation of solid and liquids has to be ensured within an appropriate time frame. For particle sizes of about 150 nm it appears questionable whether such separation can be succeeded by classical techniques, e.g. the use of syringe filters with a pore size of 0.45 μm . The aims of this thesis were to investigate the suitability of various analytical techniques in analysis of dissolution tests containing nanosized drug substance. Furthermore, a suitable analytical tool is applied to establish an in vitro - in vivo correlation of the nanosized drug fenofibrate. At first, several techniques were investigated in theory to assess their ability to ensure a rapid and complete separation of solids and liquids. The classical dialysis, turbidity measurement and UV-measurement via fiber optics were excluded from further investigation due to various reasons, e.g. the speed of separation for dialysis. The asymmetrical flow field-flow fractionation appeared to be a promising tool, but lack of equipment precluded further investigation. The ultrasonic resonance technology (ResoScan), the microdialysis and the use of centrifugal filter devices have shown to be inappropriate for...

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