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Experimental methods to study interplay of dissolution, solubility and permeability in formulation development

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Development strategy for insoluble compounds requires not only measurements of the solubility enhancement from formulations but also the assessment for the effect formulations having on permeability. An introduced dissolution-permeability (μFLUX) measurement platform allows simultaneous monitoring for both effects enabling *in-vitro* setup for early *in-vivo* predictive formulations testing. Ability to measure concentration of free (solubilized) drug *in situ* is critical necessity in formulation research because any off-line solution handling can disturb quasi-stable (kinetic) phase that low soluble compounds often form in the presence of excipients. Case studies involving 2 different detection techniques based on fiber-optic UV measurements and potentiometric free drug sensors (FDS) will be presented. These case studies will highlight: Combining dissolution and permeability assays for better formulation design, understanding the food effect on bioavailability and more realistic IVIVC; studying if solubility enhancement in the bio-relevant media leads to the same gain in the absorption and bioavailability; real time concentration monitoring of free drug in the presence of lipid passed formulations, nanoparticles and binding proteins; monitoring in real time the free API fraction released from nanoparticles and predicting absorption enhancement from nanoparticle formulations and; developing predictive *in-vitro* method to monitor powder/formulation dissolution and concomitant precipitation processes in dynamically changing biorelevant media.

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Physical fields may promote nanocarriers effectiveness in targeted drug delivery

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Nanotech resources have dramatically changed the drug delivery scenario. Due to the availability of nanocarriers which may be internalized by cells and release their cargo inside them, effectiveness is strongly enhanced and toxic side effects greatly reduced. The most critical aspect is the capability of reaching the target sites. Although the nanocarrier surface can be properly equipped with molecules with a very large affinity to the target cells, their systemic administration is '*per se*' responsible of the fact that only a small nanocarrier percentage will reach the tissue of interest. This is a limitation for the drug bioavailability and release kinetics. Local or topical delivery methods would be therefore of great interest, but are scarcely feasible unless physical fields are used to enhance penetration and drug localization. Sonication with focused or unfocused ultrasound is a well known physical mean to improve the trespassing of membranes such as the skin, the Blood Brain Barrier (BBB), etc. Also static, low intensity magnetic fields may afford effective directionality in drug delivery. Particularly, oxygen and drug-filled nanobubbles for the delivery of levo-dopa and apomorphine in Parkinsonian patients can be addressed by ultrasonication of oral or nasal mucosae to reach as more proximally as possible the BBB. The ability of the nanobubble shells of chelating heavy metals in the cerebral liquids, which are overrepresented in Parkinsonian patients would be useful for both reducing their concentration and confer to the nanobubbles some magnetic properties which may help in directioning them outside from the BBB.

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