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Nano-Structure Development of Oral Pharmaceutical Formulations in Simulated Intestine –D-contrast SANS and DLS

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Pharmaceutical drug formulations for oral delivery depict after patient intake a stepwise structure development of disintegration to micro-particles, dissolution of drug nano-complexes, interaction with bile and lipids and uptake by the intestinal membrane proteins (receptors). The processes are critical for therapy and applicability of drug and formulation, especially with hydrophobic or badly soluble drugs.
The processing of oral drug formulations was studied by neutron small angle scattering SANS with D-contrast variation, combined with DLS, with a simulator device of the human gastro-intestinal tract with SANS+DLS observation of drug nanoparticles and intermediates. A set of drugs, where oral delivery is a challenge, was investigated, e.g.: Fenofibrate, Amphotericin B, Danazol, Griseofulvin, Carbamazepine, Curcumin in combination with lipids and detergents. The biocompatibility was estimated with cell cultures. The drugs were embeded in nanoparticles and liposomes of 50-100 nm size and resolved stepwise in artificial intestinal fluid and bile. The resolution and formation of intermediated nanoparticles and excipient-drug complexes was analyzed with time resolved SANS and DLS. Substructures (domains) were localized by solvent deuterium contrast variation. The results are part of the development of novel formulations of difficult drugs upon structure investigation by SANS plus DLS in a feedback process.

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