A new look at milk as a drug delivery system, through the lens of lipid digestion

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The drug development process biases towards poorly-water soluble and often highly lipophilic drugs. One of the tools a our disposal for improving their delivery is through formulation in lipid based delivery systems. These materials often contain high amounts of surfactants and co-solvents, presenting toxicity limitations, lss of solvency on dispersion in the gastrointestinal tract and failed delivery through drug precipitation. Of course we missed the obvious- in most cases Nature has overcome these delivery challenges using milk. While milk has been previously investigated as a drug delivery system it has never progressed, in large part because of a lack of consideration of digestion as a critical component of behaviour. We have been using in situ analytical techniques to study the dissolution and delivery of poorly soluble drugs using milk, infant formula and related drinks, with a specific focus on the interaction of drug with digesting lipid components. While these systems are particularly amenable to delivery of weakly basic drugs due to ion pairing with liberated fatty acids during digestion, we have found surprisingly promising effects with acidic and non-ionisable drugs due to enhanced affinity for the colloidal structures formed during digestion enabling the drug to dissolve and remain dissolved and in an absorbable form after digestion where 'synthetic' lipid formulations have failed. The studies provide a pathway for renewed interest in milk and related materials in drug delivery and importantly offer a pediatric friendly class of excipients to better serve this neglected population in the pharmaceutical landscape.