To improve the effectiveness of the polio vaccination campaign, improvements in the thermal stability of the vaccine are being investigated. Here, inactivated polio vaccine, serotype 3 (IPV3) was characterized via a number of biophysical techniques. The size was characterized by transmission electronic microscopy and light scattering. The capsid protein conformation was evaluated by intrinsic fluorescence and circular dichroism (CD), and the D-antigen content by enzyme-linked immunosorbent assay (ELISA). The pH thermal stability of IPV3 (pH 3.0–8.0; 10°C–87.5°C) was evaluated by fluorescence, CD, and static light scattering. The transition temperatures reflect the responses, respectively, of tertiary structure, secondary structure, and size to applied thermal stress. The data were summarized as empirical phase diagrams, and the most stable conditions were found to be pH 7.0 with temperature lower than 40°C. CD detected a higher transition temperature for capsid protein than that for RNA. The effects of certain excipients on IPV3 thermal stability and antigen content were evaluated. The results of their effects, based on intrinsic fluorescence and ELISA, were in good agreement, suggesting the feasibility of applying intrinsic fluorescence as a high-throughput tool for formulation development. The study improves the understanding of IPV3 thermal stability and provides a starting point for future formulation development of IPV3 and other serotypes.

Raijada, D. et al. (2014). "Miniaturized approach for excipient selection during the development of oral solid dosage form." *J Pharm Sci* 103(3):900–908.

The present study introduces a miniaturized high-throughput platform to understand the influence of excipients on the performance of oral solid dosage forms during early drug development. Wet massing of binary mixtures of the model drug (sodium naproxen) and representative excipients was followed by sieving, drying, and compaction of the agglomerated material. The mini-compacts were subjected to stability studies at 25°C/5% relative humidity (RH), 25°C/60% RH and 40°C/75% RH for 3 months. The physical stability of the drug was affected by the storage condition and by the characteristics of the excipients, whereas all the samples were chemically stable. Force-distance curves obtained during the compression of agglomerated material were used for the comparison of compressibility of different drug-excipient mixtures. The agglomerated drug-excipient mixtures were also subjected to studies of the dissolution trend under sequential pH conditions to simulate pH environment of gastrointestinal tract. Major factors affecting the dissolution behavior were the diffusion layer pH of the binary mixtures and the ability of the excipients to alter the diffusion layer thickness. The proposed approach can be used for excipient selection and for early-stage performance testing of active pharmaceutical ingredient intended for oral solid dosage form.

Sandhu, P. S. et al. (2015). "Novel dietary lipid-based self-nanoemulsifying drug delivery systems of paclitaxel with p-gp inhibitor: Implications on cytotoxicity and biopharmaceutical performance." *Expert Opin Drug Deliv* 12(11):1809–1822.

OBJECTIVES: This work describes the development and characterization of novel self-nanoemulsifying drug delivery systems (SNEDDS) employing polyunsaturated fatty acids for enhancing the oral bioavailability and anticancer activity of paclitaxel (PTX) by coadministration with curcumin (Cu). METHODS: Preformulation studies endorsed sesame oil, labrasol, and sodium deoxycholate as lipid surfactants and cosurfactants based on their solubility for the drugs and spontaneity of emulsification to produce nanoemulsions. Further, phase titration studies were performed to identify a