Licensing Opportunity

Method for Increasing Protein Stability and Small Molecular API Solubility

Background

Problems of solubility and stability of novel small molecule drug candidates and novel protein/peptide based drug candidates lead to:

- Increased production costs
- Risk of reducing drug efficacy
- Risk of inducing toxicity or immunogenicity
- Novel treatments never reaching the market

Technology

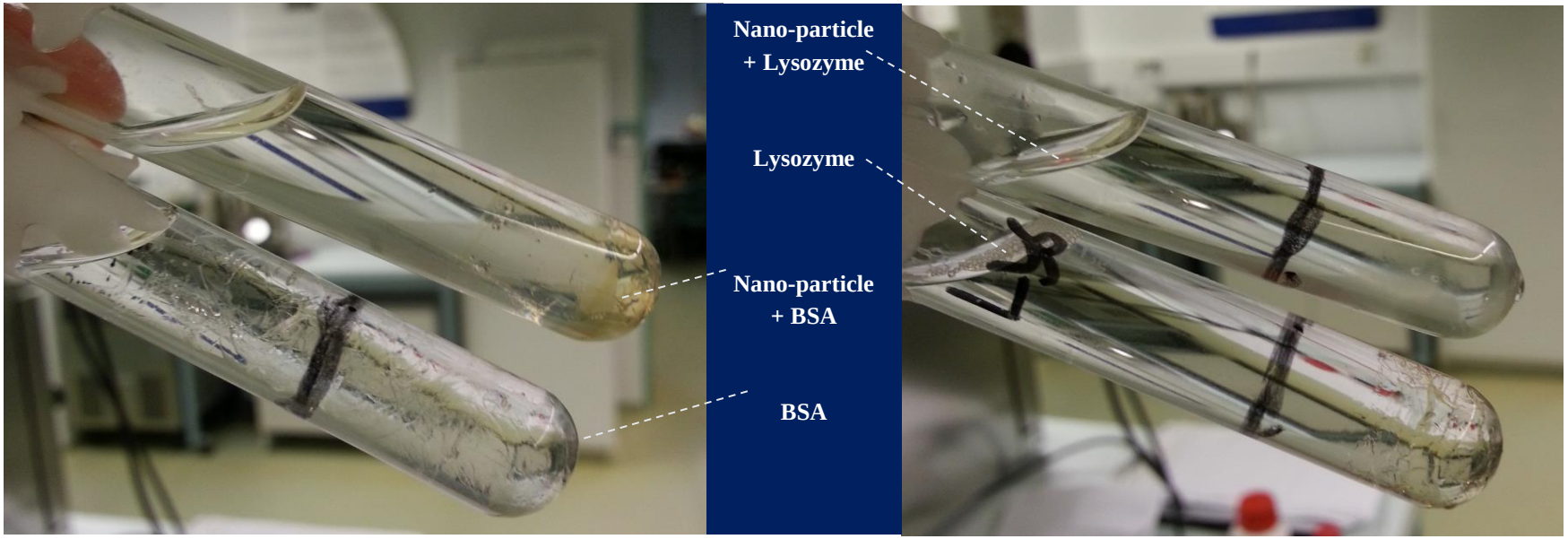
Addition of non-cytotoxic nanoparticle to formulation:

- increased protein thermo-stability
- increased solubility of poorly soluble APIs

Application

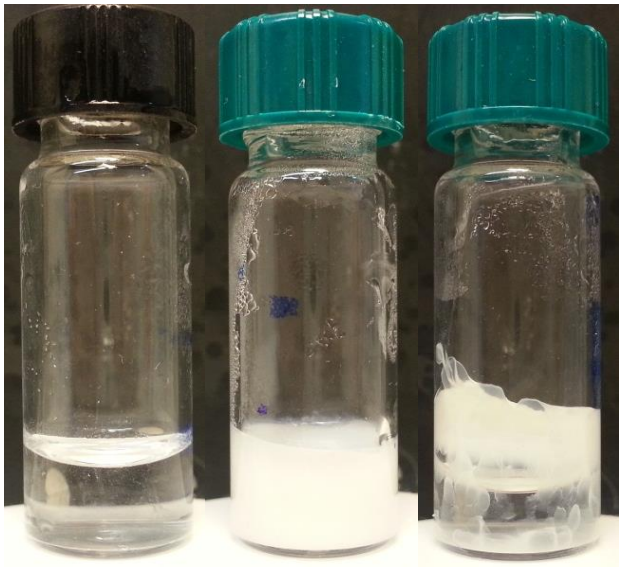
1:1 mixtures of nano-particle and protein allowed for **heating to 118 °C without visible aggregation**

Equivalent amounts (w/w) of protein and nano-particle was mixed, and diluted to about 1 % (w/w) with ultrapure water. Samples were then covered and heated to 60 °C for 24 hours, 80 °C for 24 hours and finally to 118 °C for 12 hours. Lost solvent was replaced as needed.

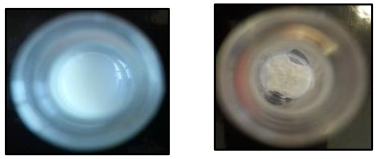


Application

Water | BSA | BSA + Nano-particle



Top-down view



1:1 mixtures of nano-particle and protein reduced visible protein-aggregation significantly upon autoclaving.

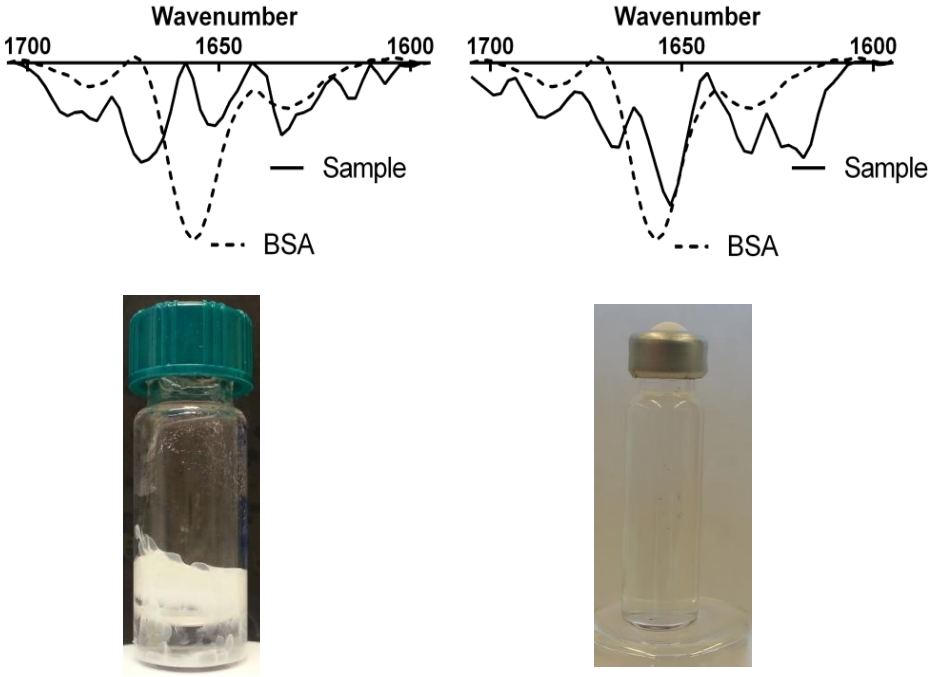
Slight optimization prevented all visible aggregation.

BSA + Nano-particle

Samples were prepared in equivalent amounts of Bovine Serum Albumin (BSA) and nano-particle, and diluted to 1 % w/w with ultrapure water.

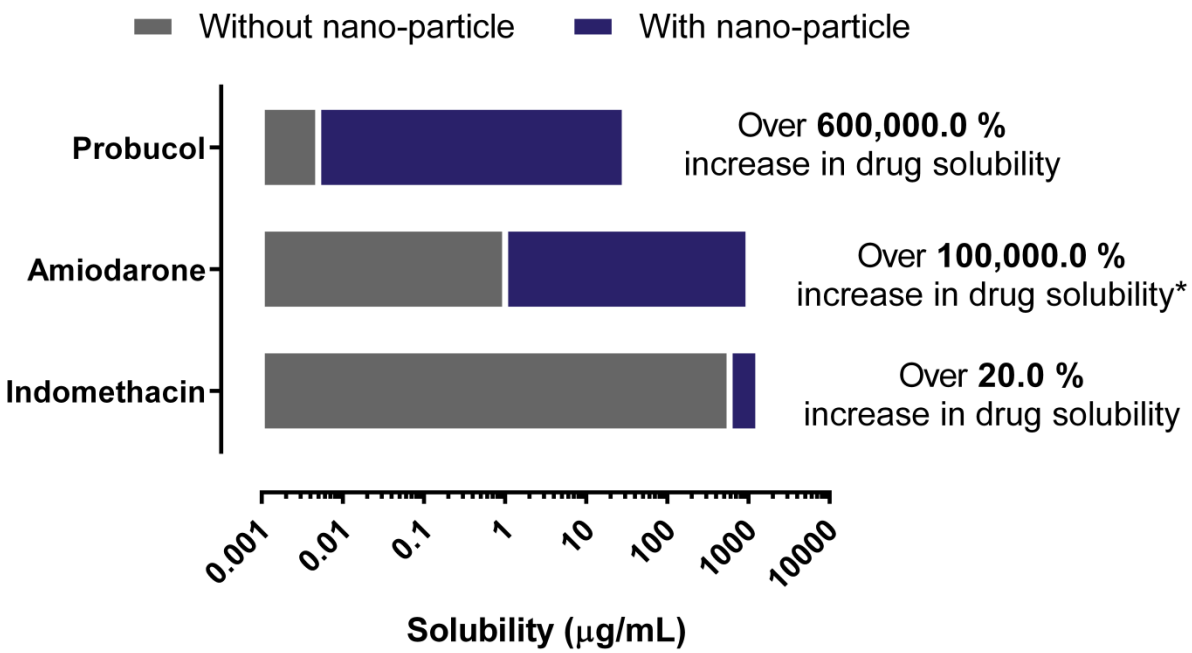
Autoclaving was conducted at 121 °C for 15 minutes.

Application



Fourier transform infrared spectroscopy (FTIR) measurements of autoclaved bovine serum albumin with nano-particle (Sample). Native BSA (dashed line) displayed for reference (BSA).
All samples were measured in triplicates.

Application



*Based on detection limit of 1 µg/mL. Actual solubility increase may be higher.

Business Opportunity

- Novel method of drastically increasing protein thermo-stability **(allowing boiling for several hours)**
- Method significantly increases solubility of poorly soluble APIs (**up to 600,000.0 % with just 1% nano-particle**)
- Requires **no additional incorporation** step and can be used in any formulation
- Made from GRAS materials and has been shown to be **non-cytotoxic**
- **Low cost** of production (<500 kr/kg material)

Patent Status

- PCT/DK2015/050162 filed 12 June 2015
- Danish priority patent application (PA 2014 70354) filed on 13 June 2014.

Commercial Enquiries:

Maj Hilligsøe
Commercial Officer
35326332 (office)
30590854 (mobile)
maj.hilligsoe@adm.ku.dk

University of Copenhagen
Research & Innovation
Technology Transfer Office
Universitetsparken 1
DK-2100 Copenhagen Ø
Denmark
www.fi.ku.dk