

BILE STABLE ORAL DELIVERY SYSTEM

Professor Nigel Slater and colleagues at the Department of Chemical Engineering and Biotechnology have developed a novel formulation technology that overcomes the bile intolerance of dried bacterial preparation. Early stage data suggest that the technology has potential applications in the fields of vaccination and probiotics.

Vaccination

- Removes the complexity of buffered liquid administration
- Allows bile tolerant delivery of live attenuated bacterial vaccines or heterologus vectored vaccines in a dried tablet or capsule form

Probiotics

- Increasing the delivery of viable 'good' bacteria in probiotic products
- Easy to manufacture, use and distribute

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Background

Live attenuated bacteria are being developed in a range of ways for example as oral vaccines against enteric pathogens, as heterologous vaccine vectors and for recolonisation of commensal enteric bacteria through probiotic approaches. The development of these products would benefit from a safe, cheap, stable and well characterised tablet or capsule formation that can deliver product to the intestine while efficiently avoiding microbicidal barriers.

Dried bacterial preparations are favoured by the industry as dry product is stable and easy to transport. Current products are either delivered as capsules with an enteric coating or are reconstituted prior to use and are given as a liquid buffered drink. Dried bacteria rapidly recover bile tolerance when reconstituted prior to delivery and while the enteric capsule coating helps to lessen the impact of stomach acids on the dried bacterial payload little research has been conducted on intestinal bile sensitivity.

Technology

The team have developed a novel formulation that combines bile acid sequestrant resins (BAR) with dried bacteria to temporarily adsorb intestinal bile acids and allow rehydration of the dried bacteria and concomitant recovery of bile resistance in the intestine.

BAR is already approved for use in humans as a generic well tolerated oral cholesterol-lowering treatment that binds bile acids in the intestine.

In vitro studies demonstrate that removal of bile acids by BAR effectively prevents toxicity of bile solutions to dried bacteria (Figure 1) and that inclusion of BAR in the drying excipient for the bacterial preparation provides effective protection of the dried bacteria from bile (figure 2).

Figure 1: Bacterial strain sensitivity to bile can be effectively reduced by mixing dried bacteria with BAR

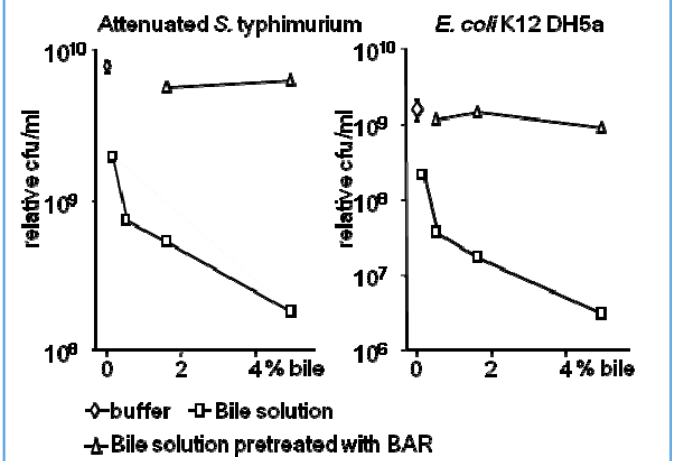
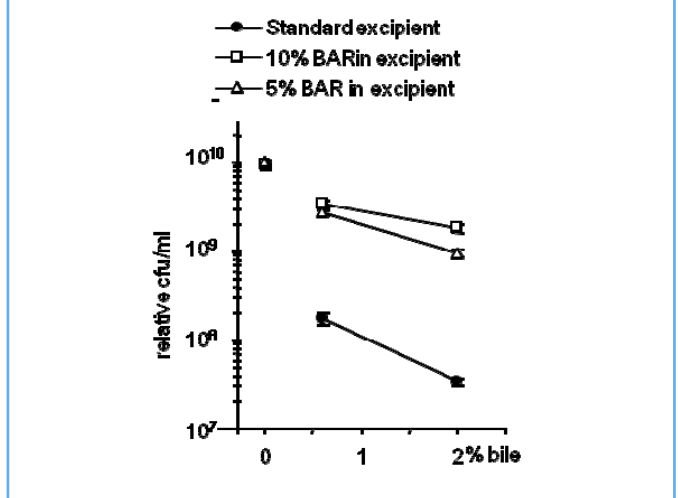


Figure 2: Inclusion of BAR in the drying excipient provides effective protection from bile enzymes.



Commercialisation

We are seeking commercial partners for field specific licensing, collaboration and development of this technology, which is protected by a priority UK patent application filed 9th January 2009.