

PHYSICAL FORM:**TECHNOLOGY TYPE:****1. What is Sponge?**

'Sponge' is a proprietary technique developed by Phares to stabilize poorly soluble drugs on highly porous carriers with large surface areas. This Phares technology is also sometimes referred to as 'porous nano matrix' (PNM). The drug is loaded into the pores usually by coating a solution of the drug in organic solvent containing stabilizers and wetting agents if required. The solution is adsorbed onto the carriers and the solvent is evaporated leaving deposited drug confined in the minute pores. Typically, the drug is in ultra fine or amorphous forms and the large surface areas exposed can enhance the dissolution remarkably compared to unformulated drug.

2. Which administration route is our Sponge technology suitable for?

Sponge is suitable for oral administration.

3. Which types of compound are suited to Sponge?

Poorly water soluble compounds with adequate solubility in organic solvents that are predisposed to amorphous formation.

4. How does Sponge increase bioavailability?

Compared to the dissolution rate of the unformulated drug alone, dissolution rates from Sponge formulations may be significantly increased. As a result, drugs that can be absorbed orally and not limited by permeability through the gastro intestinal tract are taken up more effectively.

5. Which Phares services use the Sponge technology?

During Survey, Sponge is less suitable because it needs a minimum amount of drug for reproducibly loading into pores. More traditional methods should be studied first.

Sponge is highly suitable in the Speed service (toxicity test stage), because larger gram-quantities of drug are available and loading trials can be done on a reasonable scale. The benefit of the technology is that drug loading is up to 60 % by weight thereby facilitating high dosing in animals. The beauty is that the carriers used are inert with respect to oral toxicity and can be dosed as suspensions.

During our Icebreaker Formulation Development Service, Sponge may be an ideal method for development since high drug loads are achievable using excipients which are accepted globally by regulatory authorities. From a technical stand point, the administration format is a powder for conventional HGC filling or for conversion into tablets.

6. Advantages and disadvantages of Sponge

Advantages

- High drug loads and high dissolution rates in combination with low oral toxicity of formulation components
- Possible stabilization of the amorphous form of the drug by the interaction of the drug with the surface of the carrier

Disadvantages

- Loading requires organic solvents and possibly a secondary drying step may be required depending upon the solvent and process selected
- As with all amorphous formulations, the formulated drug requires extensive real time stability testing to confirm the robustness

7. Scale-up of Sponge technology

Production of Sponge loaded with poorly water soluble drugs requires organic solvents and an infrastructure for handling organic solvents. Subsequent HGC filling and tableting use conventional solid dosage form technologies.

8. Phares Sponge expertise

Sponge is a proprietary approach developed by the Phares team. As with all of our technologies, we are able to share our inventions by making access to our IP easy and painless.

We rapidly identify the suitability of this technology for delivering compounds and compare the benefits and disadvantages with more conventional approaches.

Phares experience and expert knowledge in the area of amorphous solid dispersions extends to the development of Sponge formulations. This is supported by smart techniques that examine and characterize the physical stability of the amorphous drug in such formulations.

9. Sponge Products

Sponge is in pre-clinical and clinical testing with a variety of lipophilic poorly soluble compounds.

KEY SERVICES:



SPEED
rapid solutions for tox testing



ICEBREAKER
a clear path to the clinic