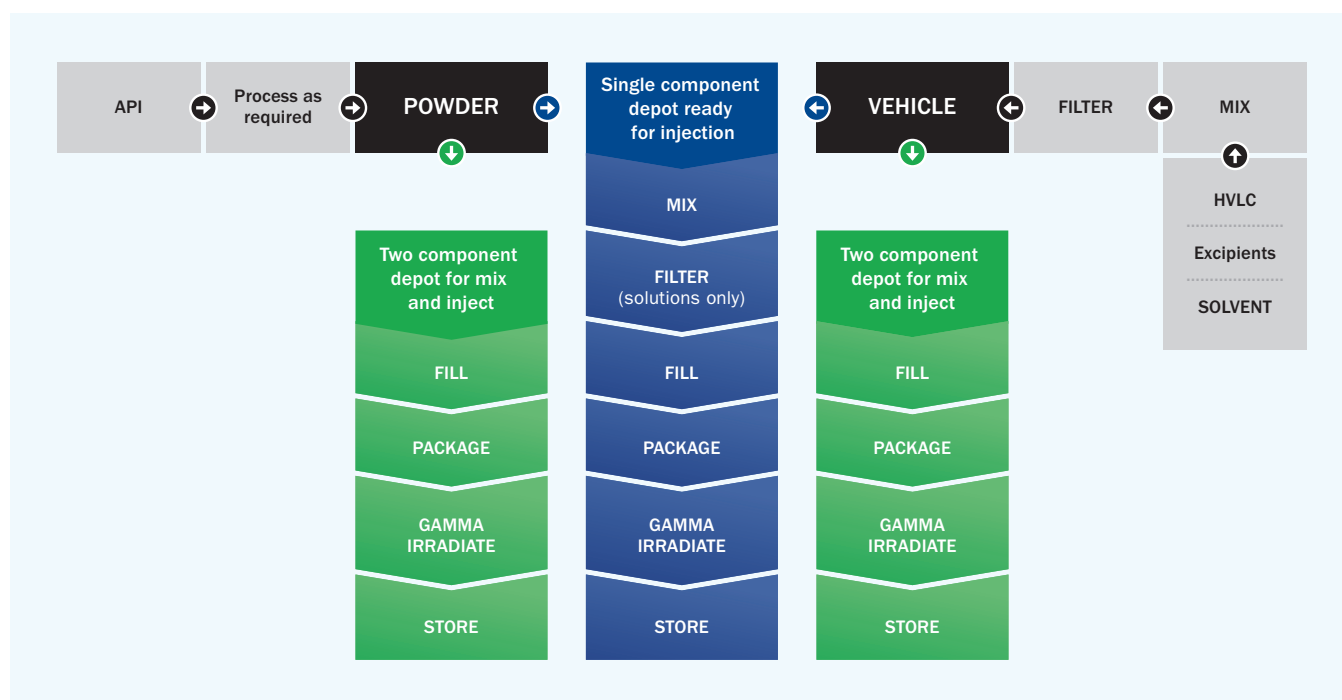


SABER[®]/CLOUD[™]

Injection Depot Technology

SABER[®] or CLOUD[™] Depot products can be manufactured using established unit operations and readily available equipment to provide for early R&D work, non-clinical, and clinical studies. Each SABER or CLOUD Depot product is comprised of a powder component and a liquid component or vehicle.

The final product presentation can be a single component depot where the 2 components are mixed to form a solution, emulsion, or suspension and filled as part of the manufacturing process as shown in the diagram or a two-component depot where the powder component and vehicle would be filled in separate containers that must be mixed at the time of use.





JET MILL



AGITATOR BEAD MILL



FREEZE DRYER



SPRAY DRYER

If the powder component requires further processing to meet the target product profile, DURECT has the capabilities to mill or micronize the component to produce particles down to sub-micron size, freeze-dried to produce an API crystal or API-excipients composition that wets easily, or spray-dried the component.

Several types of mixers are available including homogenizing mixers, vacuum mixers, and jacketed mixers for controlled heating or cooling.

Product can be filtered (if it is a solution) and filled using small-scale semi-automatic filling equipment into vials, cartridges, or syringes. DURECT also has the capability to handle potent or controlled substances in specially designed process rooms for containment and control.



ROSS MIXER



**POWERGEN
HOMOGENIZERS**



HEIDOLPH MIXER

To contain costs, DURECT purchases dedicated product contact parts for non-dedicated equipment, disposable dedicated equipment where possible, and maintains inventory of non-sterile and sterile supplies needed to manufacture products. DURECT also has the capability to design and build special tools and devices that may be needed in-house.

DURECT will package clinical supplies for GLP, non-clinical, and Phase I, Phase II, and Phase III open and blinded studies, if required. Kit assembly can be a custom design or off-the-shelf package presentation to meet the most challenging study configuration.

SABER or CLOUD Depot products can be terminally sterilized using gamma irradiation. Sterilization packaging can be synergistically designed with the final product presentation to minimize packaging costs.

DURECT can store product including controlled substances at frozen (-10 to -25 °C), refrigerated (2-8 °C), and controlled room temperature. If stability studies are required, DURECT has the capability to conduct studies at all ICH conditions.