Solution Engine 2.0

Since 1996, BioDuro has been providing solutions to the bioavailability problems of clients' poorly soluble and/or poorly permeable APIs through development of amorphous solid dispersion (ASD), Self (Micro)Emulsifying Drug Delivery Systems (S(M)DDS) and particle engineering (Micronization and nano-emulsions).

BioDuro's solution engine 2.0, provides a rational adaptive approach to formulation development using well established Van Krevelen's group contribution theories and Hansen solubility parameters to effectively predict the potential physical interactions between API and ASD polymers, plasticizers or S(M)EDD formulation components. The predictive tool minimizes the API required to less than 10 mg in the subsequent miniaturized high throughput screening (HTS) studies to confirm miscibility. BioDuro's formulation expertise combined with our in-vivo capabilities enables our team to rapidly conduct HTS studies and identify best combinations for enhancement of solubility based on physicochemical stability and in-vitro solubility results.

Our ability to start formulation development with when only milligrams of API are available combined with established methodologies delivers higher quality formulation outcomes compared to other providers in less than 4 weeks. The synergistic power of in-vitro and in-vivo adaptive formulation development saves 12 to 15 months in development activities for a phase I trial.

In addition to the solubility enhancement and increasing AUC for poorly soluble actives, BioDuro's miniaturized screening platform solution engine 2.0 allows customization of Cmax and Tmax using controlled release oral and injectable/implantable formulation development with minimal API use in animal studies.

Mini tablets (<2 mm) are manufactured and coated in commercial grade coating equipment with functional polymers for enteric/delayed release, sustained release, targeted release, colonic release, timed release or combination thereof. The oral administration of these

miniaturized tablets in-vivo increases visibility to optimize site of absorption and better control of PK profile.

For even longer sustained release formulations, BioDuro also develops biodegradable microspheres and implants that are also tested in adaptive in-vivo studies to select long acting formulations based on optimized DMPK profiles.

Solution Engine 2.0 is the most comprehensive platform in the industry to put your product in the right development path.

FASTER, BETTER, RELIABLE DELIVERY