

HOT ROD CHEMISTRY® FORMULATION SCREENING KIT



PRODUCT DESCRIPTION

Hot Rod Chemistry® (HRC) is a formulation screening kit designed to solubilize drug candidate compounds that are in the discovery stage of development and ready them for testing in animal models. The kit includes eight non-toxic, orally available formulations that are designed to increase the solubility, bioavailability and stability of drug candidates. 95% of compounds tested (>250) are soluble in at least one HRC formulation.

WHY IS THE PRODUCT INNOVATIVE?

Hot Rod Chemistry drastically improves the efficiency of drug development programs by increasing the chances of an in vitro hit becoming a viable drug candidate. This, in turn, leads to lower pharmaceutical costs passed on to the consumer and, ultimately, the availability of a larger number of efficacious drugs.

Through other innovative technologies such as combinatorial chemistry, high throughput screening, genomics and proteomics, biotechnology and pharmaceutical companies have been able to produce hundreds of thousands of compounds that demonstrate in vitro activity, that is, activity in an assay outside the living body. Nowadays, even small biotechnology and pharmaceutical companies have libraries of 500,000 compounds or more that they can screen against various disease targets.

In order to test these "hits" in an in vivo animal model, the compounds must be completely solubilized into a liquid form. This has become one of the most significant bottlenecks in a drug discovery process that is otherwise becoming more streamlined.

Typically, researchers first try to solubilize a compound in water because it is the ideal solvent. Next, the researcher might try an organic solvent such as ethanol. If neither of these solvents work, then they will try a detergent. Finally, when all else fails, they will use a universal solvent such as DMSO, which can solubilize just about anything. Unfortunately, solvents like DMSO are toxic to animals and cells and decrease the bioavailability of the molecule. Yet, even with such poor qualities, DMSO is still the most widely used chemical for solubilizing compounds for in vivo testing. This unfortunately leads researchers to lean on DMSO as a bad crutch for taking compounds to the next level. And because DMSO is toxic, if the compound becomes a viable drug candidate, it will eventually need to be re-formulated by a formulation chemist and all data collected with the DMSO formulation will have to be generated again prior to submission to the FDA.

Even under the above scenario, it is not considered economically feasible for companies to dedicate a formulations chemist to formulating compounds for such early discovery-stage testing. There is a dire need by pharmaceutical and biotechnology companies worldwide for a means by which they can reduce the escalating cost of drug development and remove the bottleneck that exists between in vitro hits and in vivo results.

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Hot Rod Chemistry solubilizes 95% of small molecule compounds with a non-toxic formulation that also contains bioavailability enhancers and stabilizers that give drug candidates the greatest opportunity for success in vivo. Compounds that are notoriously difficult to solubilize, including compounds such as Probucof, Griseofulvin and Taxol, have been formulated using Hot Rod Chemistry.

HRC can be used as part of any drug discovery program and is currently used in over 150 pharmaceutical, biotechnology and academic laboratories around the world. Using HRC, compounds can be screened for solubility for less than \$60 each. Once solubility is achieved, HRC formulated compounds can be directly dosed to animals from the HRC screening kit. Scientists can then either purchase bulk amounts of the formulation that works best for them or contract with Pharmatek Laboratories to optimize the formulation, which can then be patented and becomes the property of the client company.

Hot Rod Chemistry has also been utilized downstream in the development process. Formulation chemists looking for formulations that demonstrate better physicochemical properties have utilized HRC to increase drug potency. The utilization of the HRC kit by industry specialists in formulation development is a significant statement about the broad-reaching value of the kit.

In what has become perhaps the most compelling use of Hot Rod Chemistry, companies can re-evaluate the hundreds of thousands of compounds that have been shelved due to poor solubility and bioavailability, drastically increasing the number of compounds in the company's drug development pipeline.

Hot Rod Chemistry began as a rational approach to formulating compounds, one that took the black magic out of formulation chemistry. HRC has become a vehicle for streamlining the drug discovery process, simultaneously lowering costs and increasing the number of viable drug candidates in the drug development pipeline.

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