

MOTT'S CONTROLLED RELEASE DRUG DIFFUSION STUDIES REDUCE IN VITRO TEST TIME BY OVER 90% AND NARROW SCOPE OF ANIMAL TRIALS

OVERVIEW

Device diffusion testing is a critical step that can delay the time for an implantable drug delivery device to get through clinical trials, regulatory hurdles and ultimately, to market. Mott conducts controlled release studies for implantable devices to significantly reduce that time. Mott combines porous membrane media and established surrogate drug suspensions to conduct rapid in vitro studies. These studies can be run in as little as 1-day to accurately extrapolate controlled release of therapeutics over months. Fast and accurate results narrow the scope of in vitro testing dramatically reducing animal trial cost and time.

Mott controlled release studies guide the design criteria for next generation drug delivery technology. These diffusion studies provide reliable early assessment of drug diffusion rates and insight into form, fit and function for a device.



THE MODEL

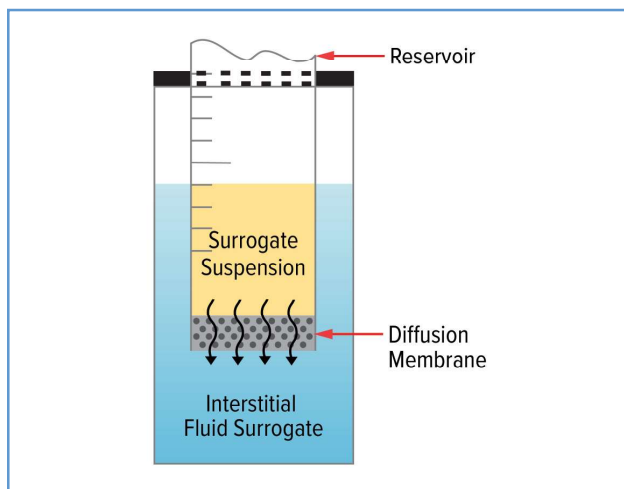


Figure 1

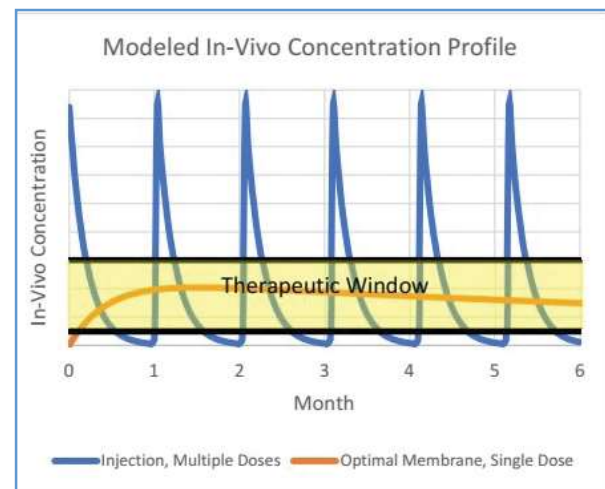


Figure 2

Figure 1 shows the general layout of the assemblies used to conduct drug diffusion studies at Mott. The surrogate (drug) suspension is contained within a reservoir fitted with various diffusion membranes to be evaluated for diffusion rates within a bath of interstitial fluid surrogate to mimic in vivo implant environments as an implanted device.

Figure 2 shows model data that can be derived from the in vitro diffusion studies to extrapolate what desired membrane characteristics would yield in vivo as compared to multiple dose injections.

PERFORMANCE INDICES

Mott has tested diffusion permeability for 1-day, 5-day and 50-day duration periods using its porous membrane technology in conjunction with surrogate medias. Studies demonstrated that the rapid 1-day model produces similar results for various drug compounds within 5% of the empirical data models.

CONCLUSION

Mott offers a fast and reliable drug diffusion testing model to illustrate the effectiveness of rapid in vitro testing...

- The diffusion study yields a diffusion constant, which correlates to element flow rate and geometry. By establishing a relationship between flow rate and diffusion constant, we can determine upper and lower limits on porosity for the application. This delivers critical guidance to feasibility and design of a device.
- Quantitatively, using only 1 day of data can extrapolate an accurate diffusion constant very close to the 50-day data set.

Mott's ability to conduct in vitro testing reduces the need to test multiple iterations of diffusion technology in vivo. Mott scientists and engineers test Mott's clinically proven porous membrane guided by therapeutic delivery requirements to identify the most suitable material for the controlled release of your therapeutic.