

DiffCORE™ Accelerating the Development of controlled Release Products

Understand

drug substance and drug product properties that influence oral in-vivo performance

Develop

tablets with a controlled release profile showing optimum efficacy and safety for the patient

Deliver

rapidly, an innovative and differentiated dosage form for clinic and market



DiffCORE™ is a proprietary technology developed by GlaxoSmithKline to facilitate the rapid development of customised controlled release tablets. Extended release is achieved by delivering drug from a tablet core through one or several apertures in an impermeable coat. The combination of the properties of the tablet core, the coat and the apertures define the drug release profile.

DiffCORE™ allows maximum flexibility to overcome difficult formulation problems that conventional matrix tablets or multi-particulate bead formulations may struggle to address.

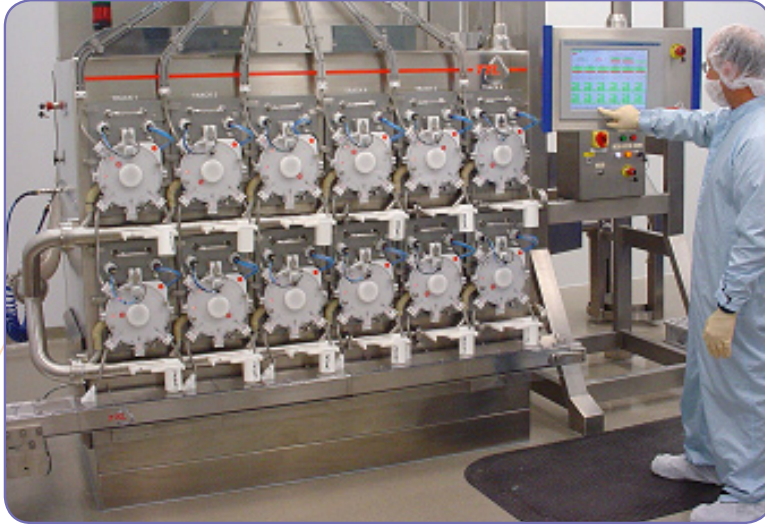
R&D Benefits

- Speed of development (often less than 3 months between project initiation and clinical supply availability)
- Release profile typically independent of tablet strength
- Scale-independent process considerably reduces technology transfer cost, complexity and risk
- Process optimisation can be done on pilot scale validated equipment
- FDA/ICH Quality by Design principles implemented from start of development
- Commercially used and regulatory approved technology

Commercial Manufacturing Benefits

- Up to 240,000 tablets processed per hour
- On-line visual inspection at the point of manufacture to 100% check presence, location, size and depth of the aperture
- Robust, industrial process (drilling yields typically in excess of 99.9%)
- GMP manufacturing facility supplying global markets

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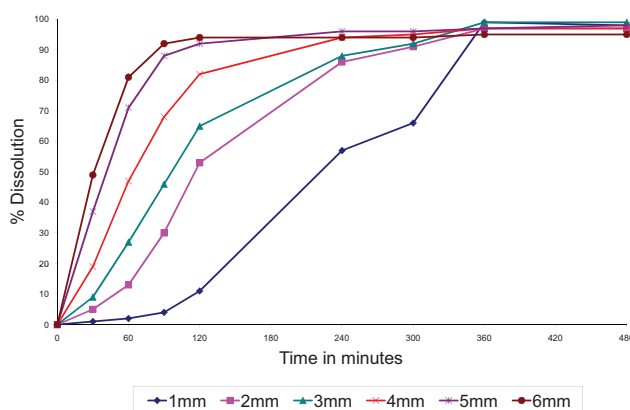
DiffCORE™ offers Key Advantages

- Speed
 - Rapid prototyping
 - Rapid fine tuning of the drug release profile using insightful in vitro performance testing
 - Rapid transfer to a robust commercial manufacturing process
- Application
 - Suitable for compounds with a broad range of solubility profiles
 - Multi-layer tablets can be formulated to further modify release or deliver multiple compounds from a single tablet
- Differentiation
 - Drilled tablets provide unique product differentiation
 - Patent protected technology

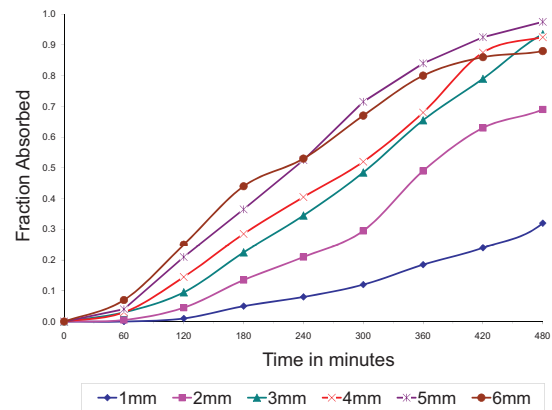
DiffCORE™ Prototyping Study Example

Formulation Selection Clinical Study - Six profiles investigated from a single enteric tablet formulation drilled with different aperture sizes

In-Vitro Dissolution Profiles



In-Vivo Plasma Concentrations



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