

PTR-076

Versatility of Aquarius™ SRX Film Coating Systems

Aquarius SRX is a family of fully formulated, solvent dispersible, ethylcellulose- (EC) based modified release film coating systems. These versatile coatings are designed for multiparticulate systems – typical substrates include drug- microcrystalline cellulose (MCC) spheronized beads and drug-layered sugar spheres. Other applications are fine particle encapsulation and matrix tablets for controlled release of high-soluble, high-dose actives.

Aquarius SRX coating systems are available in three porosity grades which can be matched to drug solubility and/or desired release duration (Table 1).

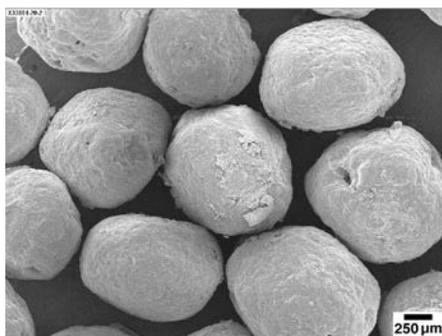
Table 1. Aquarius SRX Film Coating Systems

Type	Porosity	Drug Solubility (mg/ml at 37°C)	Application Recommendations
1	No/low	High (200 – 2000)	16 hr+ dissolution times
2	Medium	Soluble (20 – 200)	80% released in 10-16 hrs
3	High	Sparing (≤ 20)	80% released in 3-12 hrs; Elimination of burst effects in tablets

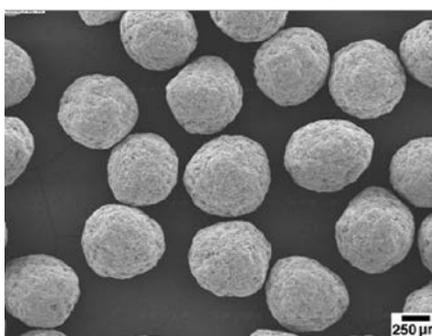
Figure 1

Substrates for Aquarius SRX Film Coating Systems

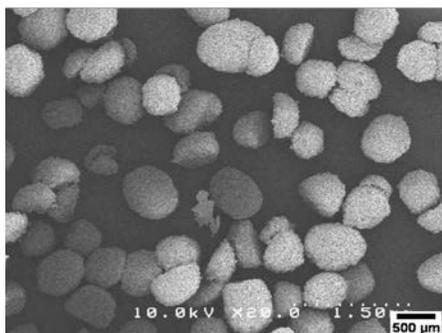
MCC-Drug Beads



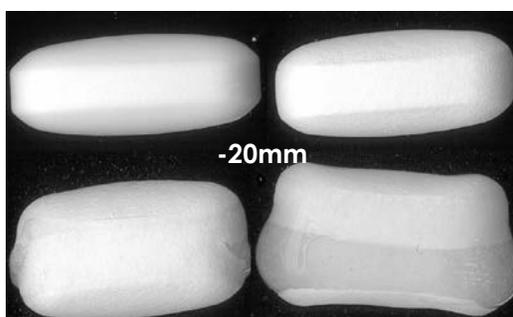
Drug Layered Sugar Spheres



Fine Particle Encapsulation



Controlled Release Matrix Tablets



Figures 2 and 3 compare spheronized drug-MCC beads and drug layered sugar spheres coated with Aquarius™ SRX coating systems. There is a significant lag time for sugar spheres. The lag times reflects the kinetics of the diffusion process leading to the build up of hydrostatic/osmotic pressure. For sugar spheres, osmotic pumping seems to predominate with no initial release until sufficient hydrostatic pressure has built up in the core via osmosis. The release duration for spheronized drug-MCC beads is considerably shorter in the initial stages, as swelling of the MCC in the spheronized beads results in greater film stress causing increased permeability.

Additionally, the Aquarius SRX coating system was found to provide predictable and robust release retardation and stable dissolution profiles (Figures 2 and 3). Lot to lot variation and starting material variation did not manifest in the final dissolution profile and is controlled with robust end product formulation (Figure 4).

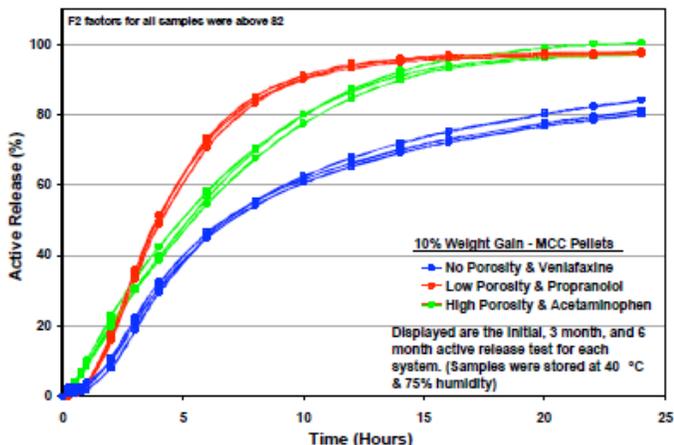


Figure 2: Release and Stability of Drug-MCC Spheronized beads coated with Aquarius SRX

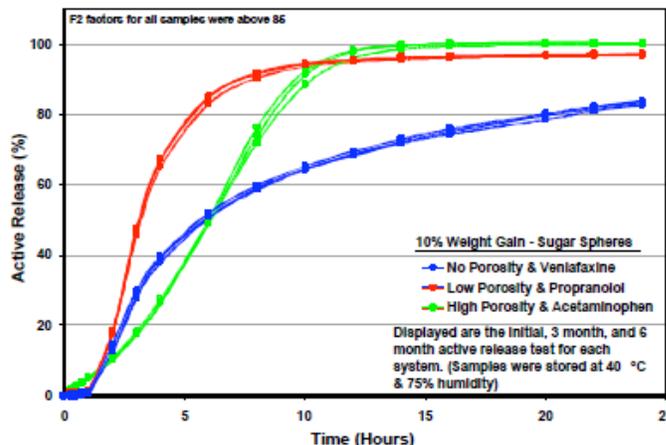


Figure 3: Release and Stability of Drug layered sugar spheres coated with Aquarius SRX

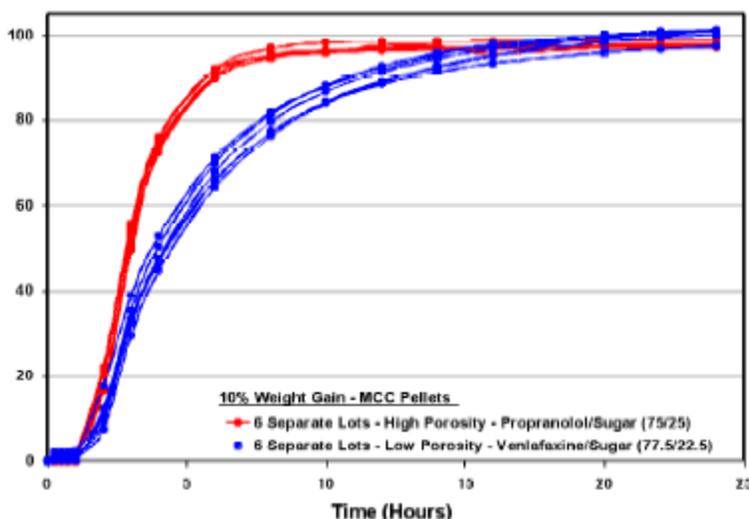


Figure 4: Lot-Lot Variability of Aquarius SRX coating systems