Advancing Pediatric ADHD Treatment: Spray-Dried Atomoxetine Microparticles for Extended-Release Therapy

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Attention-deficit/hyperactivity disorder (ADHD) affects 1 in 9 children in the United States. Current stimulant medications carry risks of elevated blood pressure, heart rate, and potential for abuse. While non-stimulants like atomoxetine offer a safer alternative, this drug is only available as an immediate-release formulation, necessitating redosing and leading to poor patient adherence. This project formulated spray-dried atomoxetine microparticles using a taste-masking polymer matrix for extended release. The polymers hydroxypropyl methylcellulose acetate succinate (HPMCAS), Eudragit S100, and beta-cyclodextrin were chosen. An eight-run extreme vertices mixture design of experiments was created to study the optimal polymer ratio. Batches were formulated from atomoxetine hydrochloride-polymer suspensions (5% w/w drug loading) using a Buchi spray-dryer. Drug release from the microparticles of all eight batches was studied in dialysis bags in simulated gastric fluid for the first 2 hours and intestinal fluid for the remainder of the 24-hour study. Samples taken at 1, 2, 4, 6, and 24 hours were analyzed via UV-Vis. Analysis of drug release data and spray-drying yield showed that a polymer ratio of 70% HPMCAS, 20% Eudragit S100, and 10% beta-cyclodextrin was optimal. This batch released approximately 60% of the drug by 2 hours and 95% by 24 hours, demonstrating extended release. Scanning electron microscopy showed an average particle size of 1-5 μm, while a colorimetric assay approximated entrapment efficiency at 103% w/w. These findings suggest that spray-dried atomoxetine microparticles can provide a non-stimulant alternative to current ADHD medications, potentially improving safety, dosing frequency, and compliance among pediatric patients.

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