



STABLE MICROCAPS[®] FORMULATION MASKS BITTER HIV DRUG FOR YOUNG CHILDREN



The powder formulation is stable in home environments, easy to administer and has flexible dosing variations for children over two and adults for whom a solid dosage form is not appropriate.

The Challenge

Adare Pharma Solutions was asked to create a taste masked, convenient dosage formulation of a very bitter API for patients two-years old and older undergoing treatment of HIV infection. As the drug would be administered in patient home settings, sub-optimal distribution and storage conditions, would need to be also considered as well as flexible dose requirements due to patient to patient weight and age variations.

The Solution

Adare scientists used Microcaps[®] taste masking technology to develop an oral powder for pediatric use approved in the US and EU, which uses a new granule formulation and includes a multi-dose bottle of taste-masked oral powder and a calibrated measuring scoop. The formulation demonstrated bioequivalence to the reference IR tablet.

The Outcome

Regulatory approvals were received from both the FDA and EMA for oral powder treatment of HIV infection with other antiretroviral agents for use in children two-years old and older. The flexible delivery system is appropriate for a range of weights and doses and is easy to administer. Dissolution profiles from multiple batches demonstrate the reproducibility of the Microcaps[®] coacervation separation process in which polymers are phased out as a liquid phase from a liquid carrier phase to form a solid coat.





TRANSFORMING DRUG DELIVERY. TRANSFORMING LIVES.

Adare Pharma Solutions is a global technology-driven CDMO providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms. Adare's specialized technology platforms provide taste masking, controlled release, solubility enhancement, and patient-centric dosing solutions. With a proven history in drug delivery, Adare has developed and manufactures more than 65 products sold by customers worldwide.

Connect with our experts today: BusDev@adareps.com

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