Cyclodextrins: Common excipients, novel application

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[^{18}F]Flurpiridaz is a novel positron emission tomography (PET) imaging tracer aimed for assessment of myocardial blood flow in patients with coronary artery disease. It is a small molecule that is practically insoluble in water and adsorbs to contact materials. Formulation studies aimed to improve the compatibility of flurpiridaz with common materials used in the drug product manufacturing process and during patient dose administration. Hydroxypropyl-β-cyclodextrin (HPβCD) was investigated as solubiliser in formulation studies on the radioactive drug product. [^{18}F]Flurpiridaz was manufactured on the FASTlab platform and formulated in three different aqueous formulations: one containing water and a radiostabiliser, the second containing water, radiostabiliser and HPβCD, and the third containing phosphate buffer and HPβCD. A co-radiostabilising effect of HPβCD was observed, while HPβCD alone was not effective as radiostabiliser. The results allowed a reduction in concentration of the main radiostabiliser after the addition of HPβCD to the formulation, while maintaining a high radiochemical stability of the drug product. The formulation also gave the added value of higher apparent solubility of [^{18}F]flurpiridaz and compatibility with materials used during drug product manufacture and patient dose administration.