

## Accepted Manuscript

Title: Juvenile Animal Testing of Hydroxypropyl- $\beta$ -Cyclodextrin in Support of Pediatric Drug Development

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**Research Highlights**

Juvenile rats received HP- $\beta$ -CD via the intravenous route at dose levels of 50, 200 and 400 mg/kg/day from postnatal day 16 to 44, and via oral gavage at 500, 1000 and 2000 mg/kg/day from postnatal day 4 to 46. The main findings were related to the renal excretion of intact HP- $\beta$ -CD and were regarded as non-adverse transient adaptive responses. In addition, following oral administration an increase in soft stools was seen which was related to osmotic water retention in the large intestine. The findings in the juvenile studies are very similar to those observed in previously performed adult rat studies at similar dose levels, same routes and similar or longer dose duration. No novel toxicity was seen in the juvenile studies.

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