**Initial Submission** Tracleer

**Reg No.** 1C 29/61 (NC)

Approval date 1 May 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
i15108/61 (N)	<b>MaV-4</b> Addition or replacement of the manufacturing site of the drug product	20 Sep 2018		