

VPA10983/031/001

Tolfine

Variation	Summary	Date
B.III.1.a.1	IAin - B.III.1.a.1 - 1. New certificate from an already approved manufacturer - B.III.1.a.1 - QUALITY CHANGES - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance For a starting material/reagent/intermediate used in the manufacturing process of the active substance For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	28/01/22