

## RESIDUAL SOLVENTS STATEMENT

According to EU Directive 2009/32 modified by (EU) 2010/59 and CPMP/ICH/283/95 Q3C.

### 3835 di-SODIUM HYDROGEN PHOSPHATE ANHYDROUS GMP

---

We hereby confirm that the product referenced above is NOT manufactured using any of the solvents currently listed in the EU Directive 2009/32 modified by (EU) 2010/59 and CPMP/ICH/283/95 Q3C.

---

Esparreguera, August 18th 2025

**Laia Galitó**  
Regulatory Affairs Specialist

