

RESIDUAL SOLVENTS STATEMENT

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

3400 *di-SODIUM HYDROGEN PHOSPHATE 12-H2O parent.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, January 20th 2025

Laia Galitó
Regulatory Affairs Specialist

