

RESIDUAL SOLVENTS STATEMENT

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

3514 EDTA, DISODIUM SALT 2-HYDRATE 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

