



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Solensia 7 mg/ml Solution for Injection for Cats

Vm 42058/5004

18 December 2025	To add an already authorised site for Physical/Chemical testing of the finished product to the manufacturing flow chart.
July 2025	To replace the current column storage solution preparation with a commercially available column storage solution for the drug substance purity control test (SE-HPLC).
01 April 2025	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.
12 February 2025	Removal of the EU Local Representatives.
14 December 2024	Addition of a site where quality control testing of the finished product takes place.
14 December 2024	To update the analytical procedures for appearance, pH, osmolality, protein concentration and endotoxin testing. To update the protocol for the generation of the WCB from the MCB. To set the column efficiency testing of the packed bed to every 8th batch prior to use. The protein A resin qualification is increased from 89 to 210 cycles.
11 May 2024	Change in the classification of AE subsequent to the VSA report.
21 February 2024	Addition of a batch release site. Minor updates to the Cordem Pharma finished product manufacturing process.
07 December 2023	SPC Section 4.6, and QRD Section 7: added anaphylaxis with frequency very rare.
02 June 2023	To update the SPC/QRD as per the National SPC/QRD template v1.
12 May 2023	Addition of a secondary packaging site of a finished product. Addition of a secondary packaging site of a finished product.
27 April 2023	Add an alternative ELISA commercial kit used to perform the registered specification testing requirement for the drug substance, frunevetmab, residual CHO host cell protein (HCP) parameter.
22 November 2022	Addition of alternative commercial cartridges and sample buffer for the Non-Reduced CE-SDS method. This method is used to perform the registered specification testing requirement for the formulated drug substance and drug product NR CE-SDS testing.
19 October 2022	Increase in batch size of active substance to 1,000 litres without process change.
20 December 2021	Changes to a test procedure for the active substance. Addition to a test procedure for the finished product. Change to in-process tests or limits applied during the manufacture of the active substance.