

Post Authorisation Assessments

AviPro Salmonella Duo Lyophilisate for Use in Drinking Water Vm 00879/4188

• 04 May 2024 Changes to a non-significant specification parameter of a starting material used in the manufacturing process of the active substance. • 19 March 2024 Changes to a non-significant specification parameter of a starting material used in the manufacturing process of the active substance. • 19 March 2024 Changes to a non-significant specification parameter of a starting material used in the manufacturing process of the active substance. • 31 May 2022 Repeat Use to add one CMS • 23 June 2021 Changes in the manufacturing process of the finished product. Change in the specification limits of the finished product. Change of MAH from Lohmann Animal Health GmbH, Heinz-Lohmann-Straße 4, D-27472 Cuxhaven, to Elance Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom. • 16 September 2020 Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Update of format of Part 2 of the dossier. • 05 June 2019 Change in the safety database of an existing pharmacovigilance system as described in the DDPS. • 12 July 2017 Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance.	•	1 04 May 2024	
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active substance.			•
07 March 2017 Departules application to add one new March or State		07 March 0047	
27 March 2017 Repeat Use application to add one new Member State.	•		
28 July 2016 Renewal – UK CMS	•		
17 December 2014 Minor change to a test procedure for an excipient.	•		
21 November 2014 Update to the DDPS.	•	-	
19 March 2014 Addition of turkey as a target species.	•	19 March 2014	Addition of turkey as a target species.
07 February 2014 Changes to an existing pharmacovigilance system.	•	07 February 2014	Changes to an existing pharmacovigilance system.
16 May 2012 Change to the name of the MA holder, change to the	•	16 May 2012	
name of the active substance manufacturer and change			•
to the name of the finished product manufacturers			
responsible for packaging, quality control and batch			
release.			