Veterinary Medicines Directorate

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Post Authorisation Assessments

Apralan Soluble Powder for Use in Drinking Water/Milk Replacer for Pigs, Calves, Chickens and Rabbits

•	06 May 2021	Deletion of manufacturer responsible for batch release.
•	07 May 2020	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	03 December 2019	Addition of a site where batch control/testing takes place.
•	09 October 2019	Update of the dossier following a referral procedure.
•	16 July 2019	Addition of a secondary packaging site of the finished product.
•	27 June 2019	Addition of a secondary packaging site of the finished product.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	28 March 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	25 September 2018	Increase in batch size (up to 10-fold) of the finished product. Addition of a site where testing takes place. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	28 August 2018	Changes to the SPC/product labelling/package leaflet following an Article 34 referral.
•	02 August 2018	Update of the quality dossier following a Commission Decision following the procedure Articles 34 of Directive 2001/82/EC (referral procedure) – the change implements the outcome of the referral.
•	24 October 2017	Minor change in the manufacturing process of the active substance.
•	28 September 2016	Volume adjusted to change in bulk volume activity. Specifications updated in regard to bulk volume activity. Specifications updated in regard to bulk volume activity. Volume adjusted to change in bulk volume activity.
•	16 July 2014	Addition of an in-process test applied during manufacture of the active substance and minor change to the manufacturing process for the active substance.
•	29 August 2013	Change in the manufacturing process of the active substance Change to comply with the Ph. Eur. or national Pharmacopoeia of a member state

•	21 August 2013	Change in batch size of the finished product
•	13 June 2012	Change in specification parameters for a component of the immediate packaging
•	08 February 2012	Change in specification of the immediate packaging
•	15 June 2010	Minor change in the manufacturing process for the active substance
•	11 December 2008	Changes to the SPC and Product Literature to bring in line with new legislation Removal of a manufacturing site for pert of the manufacturing process of the finished product
•	04 January 2008	Change of address of the MAH
•	23 April 2007	Renewal
•	03 July 2003	Renewal
•	13 September 2002	Change of name of assembler of dosage form Deletion of a manufacturer of active substance and dosage form
•	17 July 2000	Change of non-sterile containers
•	20 June 2000	Change in shelf life
•	12 January 1998	Change of MAH
•	09 October 1997	Additional presentation
•	02 April 1997	Renewal
•	26 March 1997	Change in manufacturing process
•	04 September 1996	Change in name/address of MAH
•	16 June 1993	Change in therapeutic indications
•	20 October 1992	Review