Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Solacyl 1000 mg/g, Powder for Use in Drinking Water/Milk for Cattle and Pigs

Vm 16849/5004

•	02 July 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	02 November 2023	Change in the specification of “clarity of solution” at release and at shelf-life.
•	22 September 2023	One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
•	07 February 2019	Repeat Use application to add 6 new member states
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 September 2018	Variation to update the ASMF.
•	23 February 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Change to in-process limit applied during the manufacture of the finished product.
•	02 November 2016	Mock-ups approved. Change of distributor.
•	01 May 2013	Deletion of manufacturing site for the active ingredient.
•	06 March 2013	Change of QPPV and contact details for the QPPV of an existing pharmacovigilance system.
•	04 January 2013	Renewal procedure – The Netherlands as RMS.
•	15 August 2012	Variation to add an immediate packaging material.
•	13 January 2010	Change of distributor.
•	26 November 2009	To submit mock-ups for approval for an already authorised pack size of 100g.
•	05 November 2008	To bring the SPC and labels in line with the new legislation