Veterinary Medicines Directorate

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Post Authorisation Assessments

Ingelvac MycoFlex Suspension for Injection for Pigs

Vm 08327/5039

•	18 May 2024	Approval of mock-ups.
•	02 February 2024	Alignment of porcine serum testing information in text and summary table. (NI)
•	27 December 2023	Modification of the preparation of the medium used in the manufacturing process of the active substance. (GB)
•	22 December 2023	Alignment of porcine serum testing information in text and summary table. (GB)
•	08 December 2023	Editorial changes referring to deletion of information covered by GMP. (NI)
•	11 August 2023	Editorial changes referring to deletion of information covered by GMP. (GB)
•	24 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	24 February 2023	To increase the maximum release titre of the vaccine from 4.61 RP to 6.94 RP per dose.
•	17 January 2023	To increase the maximum release titre of the vaccine from 4.61 RP to 6.94 RP per dose.
•	24 September 2021	Change in the name of the manufacturer of the finished product.
•	29 July 2021	Change in the number of units (e.g. ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product Change in the number of units (e.g. ampoules*, etc.) in a pack within the range of the currently approved pack sizes of the finished product Change in the number of units (e.g. ampoules*, etc.) in a pack within the range of the currently approved pack sizes of the finished product Change in the number of units (e.g. ampoules*, etc.) in a pack within the range of the currently approved pack sizes of the finished product Change in the number of units (e.g. ampoules*, etc.) in a pack within the range of the currently approved pack sizes of the finished product Change in the number of units (e.g. ampoules*, etc.) in a pack within the range of the currently approved pack sizes of the finished product Changes to the labelling and package leaflet Addition of a new container for the finished product.
•	03 December 2020	Change in the name of the manufacturer of the finished product.

•	24 November 2020	Minor change in the manufacturing process of the finished product.
•	24 November 2020	Minor change in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance.
•	21 September 2020	Changes to a test procedure for the active substance.
•	17 December 2019	Change of a test procedure for the active substance.
•	28 October 2019	Deletion of a test procedure for the active substance used in the manufacturing process of the active substance if an alternative test procedure is already authorised. Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	10 June 2019	Change in the name of a manufacturer of active substance. Change in the name of the manufacturer of the finished product.
•	06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	07 November 2018	Changes to the labelling.
•	07 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	14 May 2018	Changes to a test procedure (including addition) for the active substance.
•	14 December 2017	Deletion of manufacturing site for an active substance. Replacement of a secondary packaging site of the finished product.
•	23 August 2017	Minor change in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance.
•	03 May 2017	Editorial changes to part 2C
•	21 December 2016	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance Minor change to an approved test procedure for the

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•	01 December 2016	Tightening of in-process limits applied during the manufacture of the finished product.
•	01 November 2016	Change in the address of the local representative in Poland.
•	26 April 2016	Change in test procedure for the immediate packaging of the finished product
•	24 February 2016	Change in the shelf life of the finished product from 21 months to 2 years.
•	03 November 2015	Update of the DDPS. Addition of a new site of manufacture.
•	04 September 2014	Change in test procedure for the finished product.
•	29 May 2014	Renewal – UK comment.
•	19 August 2013	Replacement of a manufacturer of a secondary packaging site
•	21 December 2012	Addition of an alternative manufacturing site for the secondary packaging of the finished product.
•	28 September 2012	Addition of a test method for in-process sterility testing; addition of in-use shelf life; deletion of APHIS number (USA requirement) from the packaging materials.
•	29 March 2012	Change in the dimensions or shape of the immediate package.
•	11 October 2011	To increase the batch size.
•	11 October 2011	To increase the antigen production scale.
•	13 July 2011	Changes to the labelling and package leaflet which are not connected to the Summary of Product Characteristics.
•	08 March 2011	To adjust the SPC/PIL texts from Ingelvac MycoFLEX to those approved for Ingelvac CircoFLEX, in relation to the simultaneous use of both vaccines, in order to provide harmonisation between the SPCs of both products
•	08 July 2010	To change the colour of the flip-off cap. (Primary packaging material, not in contact with the finished product).
•	15 April 2010	To replace the vaccine reference for potency test.
•	06 October 2009	To add an alternative manufacturing site for secondary packaging of the finished product