Veterinary Medicines Directorate

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Post Authorisation Assessments

Combiclav Suspension for Injection

Vm 02000/4238

09 January 2025	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance.
03 July 2023	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.
20 December 2022	Editorial changes to part 2b of the dossier.
22 November 2022	Submission of a new Ph. Eur certificate of suitability for an active substance.
28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
11 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
14 April 2021	Minor change in the manufacturing process of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
08 July 2020	Minor changes to an approved test procedure of the finished product.
08 July 2020	Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers.
14 August 2019	Replacement of a supplier of packaging components or devices.
30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
17 January 2019	Minor changes to an approved test procedure of the finished product.
17 January 2019	Introduction of a new site of manufacture.

27 July 2018	Changes to the labelling and package leaflet. Update distributor details on the QRD text.
19 July 2018	Replacement of a secondary packaging site of the finished product.
02 July 2018	Change of specification of a former non Pharmacopoeial excipient to comply with the Ph. Eur. Specifications. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
23 February 2016	Deletion of a manufacturing site for the active. Submission of an updated certificate of suitability. Submission of a new certificate of suitability.
21 November 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved active substance manufacturer.
08 January 2009	Changes to the SPC and Product Literature to bring in line with new legislation
08 August 2008	Renewal
15 July 2008	Submission of updated Ph. Eur. Certificates of Suitability for active substances from an already approved manufacturer
19 June 2008	Deletion of a manufacturer of an active substance
16 January 2008	Addition of a manufacturer of an active substance Addition of a manufacturer of an active substance
28 March 2007	Change of legal category from POM to POM-V
24 August 2005	Addition of an indication for use with Combiclav LC