



Post Authorisation Assessments

Pimocard 2.5 mg Flavoured Tablets for Dogs Vm 16849/3021

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| 03 February 2026 | <p>Change in batch size of intermediate used in the manufacturing process of the active substance: up to 10-fold increase compared to the originally approved batch size.</p> <p>Change in batch size of intermediate used in the manufacturing process of the active substance: up to 10-fold increase compared to the originally approved batch size.</p> <p>Deletion of a non-significant specification parameter of an active substance.</p> <p>Deletion of a supplier of a starting material for an active substance.</p> <p>Minor change in the manufacturing process of an active substance.</p> <p>Change in the specification limits of a starting material used in the manufacturing process of the active substance.</p> |
| 19 December 2025 | Minor change to the restricted part of an Active Substance Master File. |
| 23 March 2022 | Minor change in the manufacturing process of the finished product. |
| 17 August 2021 | <p>Increase in batch size (to 6.0 kg) of the active substance used in the manufacturing process of the active substance.</p> <p>Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.</p> <p>Change in the manufacture of the active substance.</p> <p>Extension of a re-test period of the active substance.</p> |
| 31 December 2019 | <p>Addition of a secondary packaging site of the finished product.</p> <p>Addition of a primary packaging site of the finished product.</p> <p>Addition of a manufacturing site of the finished product.</p> |
| 24 January 2019 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| 17 January 2019 | Addition of a manufacturer responsible for batch release including batch control/testing. |
| 30 August 2018 | Change in RMS from UK to NL. |
| 17 July 2018 | Repeat use MRP to add 4 new CMS |
| 05 October 2017 | Renewal – UK as RMS. |

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| 05 August 2016 | Change in distributor details. |
| 22 January 2015 | Change in the name of a supplier of a starting material of the active substance. Change to the specification limits. Addition of a new specification parameter with its corresponding test method. |
| 04 December 2014 | To increase the batch size of the active substance. To change the test procedure of the active substance. Change to the manufacturing process. Addition of an alternative supplier/manufacturer for the starting material of the active substance. Addition of a supplier for the starting material of the active substance. |
| 04 December 2014 | To add a manufacturing site responsible for all activities to produce Pimocard, including primary and secondary packaging, batch control testing and batch release. Minor change in the manufacturing process. Change to the limits of an excipient. |
| 12 July 2013 | Change in QPPV and QPPV contact details. |