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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Purevax RCP Lyophilisate and Solvent for Suspension for Injection

Vm 04491/5053

14 January 2025	This variation was aimed to change the name and address change of this sub-contractor.
20 December 2024	Change in the specification parameter of the finished product to describe more accurately the appearance of the product.
13 August 2024	G.I.18 update of the product information in line with version 2 of the National template.
25 July 2024	Minor editorial changes to part 2 of the dossier.
28 April 2024	To widen the specification of the residual humidity test for the Purevax RCP lyophilisate, at release and at the end of shelf-life.
24 October 2023	Update to the description of starting materials of biological origin.
03 October 2023	Minor changes to processes relating to the equipment.
July 2023	To add an alternative method for the multiplication of CrFK cells in biogenerator.
27 June 2023	Addition of a secondary packaging site of a finished product.
15 June 2023	Editorial changes to Part 2 of the dossier if inclusion in an upcoming procedure concerning Part 2 is not possible.
27 April 2023	Change in the storage temperature of the MCB and WCB. Update to the quality control testing of the IRC5 WCB and MCB+20 cell lines used for the manufacturing of the feline panleucopenia active ingredient.
26 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
09 March 2023	Replace the buffered physiological saline solution used to make the finished product with water for injections.
20 December 2022	To add use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance.
03 November 2022	Editorial change of the range for osmolality for stabiliser 49 to 320–356 mOsm/kg.
18 August 2022	Deletion of a manufacturer of an active substance.
16 August 2022	Modification of the conductivity test limit of acceptance carried out on sterile diluent to less than or equal to 25 µS/cm.
05 August 2022	To increase the maximum release titre of the feline herpesvirus component of Purevax vaccines from 10^6.2 CCID50/dose to 10^6.5 CCID50/dose and to align the titre across the documents to be expressed in units/dose.
06 May 2022	Changes to SPC & product literature following a periodic safety update report (PSUR)
17 March 2022	Change of a test procedure for the active substance. Changes in the manufacturing process of the active substance.
25 June 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product.

	Deletion of a non-significant specification parameter of the finished product.
04 June 2021	Change in the manufacturing process of the active substance.
26 March 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.