



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Purevax RCPCh Lyophilisate and Solvent for Suspension for Injection Vm 04491/5055

•	24 October 2023	Update to the description of starting materials of biological origin.
•	05 October 2023	Minor changes to processes relating to the equipment.
•	14 July 2023	To add an alternative method for the multiplication of CrFK cells in biogenerator.
•	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.
•	27 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	30 March 2023	G.I.18 Update of the SPC/QRD texts to the last GB Template.
•	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} CCID ₅₀ /dose to 10 ^{6.5} CCID ₅₀ /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.