VPA22622/009/002

Felimazole 5 mg Coated Tablets for Cats

Variation	Summary	Date
Vet - B3 m)	VNRA - Vet - B3 m) - - Vet - B3 m) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of an excipient	12/06/26
Vet - B3 d)	VNRA - Vet - B3 d) - - Vet - B3 d) - Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance;— a starting material;— an intermediate or reagent used in the manufacturing process of the active substance	27/03/26
Vet - B44 a)	VNRA - Vet - B44 a) - - Vet - B44 a) - Submission of a Ph. Eur. CEP for:— active substance;— starting material, reagent or intermediate used in the manufacturing process of the active substance;— excipient - Updated cerificate	27/03/26
Vet - F.II.a.3 z)	VRA-R - Vet - F.II.a.3 z) - - Vet - F.II.a.3 z) - Changes in the composition (excipients) of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	30/01/26
Vet - B3 k)	VNRA - Vet - B3 k) - k) Deletion of a non-significant in-process test (finished product manufacture) - B3 k) Changes to the quality part of the dossier: Deletion of a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	10/06/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	26/03/25
Vet - B45	VNRA - Vet - B45 - Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile active substance, starting material, reagent or intermediate, excipient - B45 Changes to the quality part of the dossier: Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: — active substance; — starting material, reagent or intermediate used in the	20/02/25

	manufacturing process of the active substance; — excipient	
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	02/10/24