

VPA10521/007/002

Drontal Cat XL Film-coated Tablets

Variation	Summary	Date
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 certificate	03/09/25
Vet - B24 a)	VNRA - Vet – B24 a) - B24 Replacement or addition of a manufacturer responsible for a) - B24 Replacement or addition of a manufacturer responsible for a)- batch release including batch control or testing of a sterile or non-sterile finished product	21/11/24
Vet - B20	VNRA - Vet - B20 - Replacement or addition of a primary packaging site of a non-sterile finished product - B20 Changes to the quality part of the dossier: Replacement or addition of a primary packaging site of a non-sterile finished product	21/11/24
Vet - B3 n)	VNRA - Vet - B3 n) - n) Deletion of a non-significant specification parameter (finished product) - B3 n) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) in the specification parameters or limits of the finished product	21/11/24
Vet - B47 a)	VNRA - Vet - B47 a) - a) Change of specification(s) of a former non EU Pharmacopoeial active substance, excipient or active substance starting material to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - B47 a) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change of specification(s) of a former non EU Pharmacopoeial active substance, excipient or active substance starting material to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State	21/11/24
Vet - B19	VNRA - Vet - B19 - Change in coating weight of oral dosage forms or change in weight of capsule shells for a solid oral pharmaceutical form - B19 Changes to the quality part of the dossier: Change in coating weight of oral dosage forms or change in weight of capsule shells for a solid oral pharmaceutical form	21/11/24
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuring device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished	21/11/24

	product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	
Vet - B35 b)	VNRA - Vet - B35 b) - b) Addition of a new specification parameter to the specification with its corresponding test method - B35 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of the immediate packaging of the finished product: — addition of a new specification parameter to the specification with its corresponding test method	21/11/24
Vet - B21	VNRA - Vet - B21 - Replacement or addition of a secondary packaging site of a finished product - B21 Changes to the quality part of the dossier: Replacement or addition of a secondary packaging site of a finished product	21/11/24
Vet - B26 c)	VNRA - Vet - B26 c) - c) Downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical forms or to non-sterile liquid based pharmaceutical form - B26 c) Changes to the quality part of the dossier: Change in the batch size (including batch size ranges) of the finished product: — downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical forms or to non-sterile liquid based pharmaceutical form	21/11/24
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 manufacturing process of the active substance; — excipient	21/11/24
Vet - B36	VNRA - Vet - B36 - Change in test procedure for the immediate packaging of the finished product (including replacement or addition) - B36 Changes to the quality part of the dossier: Change in test procedure for the immediate packaging of the finished product (including replacement or addition)	21/11/24
Vet - B44(Do not use)	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	21/11/24
Vet - B26 a)	VNRA - Vet - B26 a) - a) Up to 10-fold increase	21/11/24

	<p>compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form - B26 a)</p> <p>Changes to the quality part of the dossier: Change in the batch size (including batch size ranges) of the finished product: — up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form</p>	
Vet - B3 t)	<p>VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t)</p> <p>Changes to the quality part of the dossier: Deletion of a Ph. Eur. CEP — for an active substance; — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient</p>	21/11/24
Vet - B3 f)	<p>VNRA - Vet - B3 f) - f) Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form - B3 f)</p> <p>Changes to the quality part of the dossier: Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form</p>	21/11/24
Vet - F.II.d.1 z)	<p>VRA-R - Vet - F.II.d.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.d.1 z) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021</p>	21/11/24
Vet - F.II.b.3 a)	<p>VRA-R - Vet - F.II.b.3 a) - a) Minor change in the manufacturing process - F.II.b.3 a) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Minor change in the manufacturing process</p>	21/11/24
Vet - F.II.b.1 c)	<p>VRA-R - Vet - F.II.b.1 c) - c) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products - F.II.b.1 c) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products</p>	21/11/24
Vet - F.II.b.1 c)	<p>VRA-R - Vet - F.II.b.1 c) - c) Site where any</p>	21/11/24

	<p>manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products - F.II.b.1 c) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products</p>	
Vet - F.II.a.3 z)	<p>VRA-R - Vet - F.II.a.3 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.a.3 a) Quality Changes - Finished Product - Description and composition - 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 EMA/CMDv/7381/2021</p>	21/11/24
Vet - C1	<p>VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)</p>	31/03/23
Vet - C6	<p>VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17</p>	31/03/23