VPA10521/009/001

Drontal Plus XL Flavour Tablets for Dogs

Variation	Summary	Date
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	17/08/26
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - - Vet - F.I.f.1 - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	25/05/26
Vet - F.III.1 a) z.	VRA-R - Vet - F.III.1 a) z. - - Vet - F.III.1 a) z. - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability - For an active substance, For a starting material/reagent/intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	11/11/25
Vet - A1 b)	VNRA - Vet - A1 b) - b) Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. - A1 b) Administratvie changes: Change in the name or address or contact details of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where ecified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	26/03/25
Vet - B4 c)	VNRA - Vet - B4 c) - c) Introduction of a new site of micronisation for the manufacturer of the active substance (including relevant quality control testing sites) - B4 c) Changes to the quality part of the dossier: Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate) - introduction of a new site of micronisation for the manufacturer of the active substance (including relevant quality control testing sites)	21/03/25
Vet - B3 d)	VNRA - Vet - B3 d) - d) Deletion of a non-significant specification parameter (active substance, starting material, intermediate - 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	18/06/24

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	18/06/24
Vet - B4 c)	VNRA - Vet - B4 c) - c) Introduction of a new site of micronisation for the manufacturer of the active substance (including relevant quality control testing sites) - B4 c) Changes to the quality part of the dossier: Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate) - introduction of a new site of micronisation for the manufacturer of the active substance (including relevant quality control testing sites)	18/06/24
Vet - B11 b)	VNRA - Vet - B11 b) - b) Tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance - B11 b) Changes to the quality part of the dossier: Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance — tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	18/06/24
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	18/06/24
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	18/06/24
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	18/06/24
Vet - B34	VNRA - Vet - B34 - Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product - B34 Changes to the quality part of the dossier: Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product	18/06/24
Vet - B35 b)	VNRA - Vet - B35 b) - b) Addition of a new specification	18/06/24

	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	
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	18/06/24
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	18/06/24
Vet - B3 d)	VNRA - Vet - B3 d) - d) Deletion of a non-significant specification parameter (active substance, starting material, intermediate - 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	04/06/24
Vet - B3 t)	VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t) 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	31/05/24
Vet - B3 t)	VNRA - Vet - B3 t) - t) Deletion of a Ph. Eur. CEP - B3 t) 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	31/05/24
Vet - F.I.b.2 b)	VRA-R - Vet - F.I.b.2 b) - b) Other changes to a test procedure (including replacement or addition) for the active substance - F.I.b.2 b) Quality Changes - Active Substance - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance	31/05/24
Vet - F.I.b.2 b)	VRA-R - Vet - F.I.b.2 b) - b) Other changes to a test procedure (including replacement or addition) for the active substance - F.I.b.2 b) Quality Changes - Active Substance - Control of active substance - Change in test procedure for active substance	31/05/24

	or starting material/reagent/intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance	
Vet - F.II.b.1 c)	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	31/05/24
Vet - F.II.b.1 z)	VRA-R - Vet - F.II.b.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.b.1 z) Quality Changes - Finished Product -Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	31/05/24
Vet - F.II.d.1 z)	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	31/05/24
Vet - C1	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)	31/03/23
Vet - C6	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	31/03/23