VPA10521/005/001

Droncit Tablets 50 mg

Variation	Summary	Date
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
Vet - B27 b)	VNRA - Vet - B27 b) - b) Addition of a new in-process test and limits - B27 b) Changes to the quality part of the dossier: Change to in-process tests or limits applied during the manufacture of the finished product: — addition of a new in-process test and limits	05/12/22
Vet - B26 a)	VNRA - Vet - B26 a) - a) 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 - B26 a) 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	05/12/22
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	05/12/22
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	05/12/22
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	05/12/22
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:	05/12/22

	Change in test procedure for the immediate packaging of the finished product (including replacement or addition)	
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	05/12/22
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	05/12/22
Vet - B24	VNRA - Vet - B24 - Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non- sterile finished product - B24 Changes to the quality part of the dossier: Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non- sterile finished product	05/12/22
Vet - F.II.b.3 z)	VRA-S - Vet - F.II.b.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.b.3 z) 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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	05/12/22
Vet - F.II.b.5 z)	VRA-S - Vet - F.II.b.5 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.5 z) Quality Changes - Finished Product -Manufacture - Change to in-process tests or limits applied during the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	05/12/22
Vet - F.II.d.1 z)	VRA-S - 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	05/12/22
Vet - F.II.b.1 c)	VRA-S - 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	05/12/22
Vet - F.II.e.5 a)	VRA-S - Vet - F.II.e.5 a) - a) Change in the number of units (e.g.	05/12/22

	tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes - F.II.e.5 a) Quality Changes - Container closure system -Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes	
Vet - B44	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	11/05/22