VPA10509/006/001

Rhemox 500 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production

Variation	Summary	Date
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	03/10/23
Vet - F.II.d.1 d)	VRA-R - Vet - F.II.d.1 d) - d) Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product) - F.II.d.1 d) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing (microbial testing of finished product)	03/10/23
Vet - F.II.d.1 c)	VRA-R - Vet - F.II.d.1 c) - c) Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue - F.II.d.1 c) Quality Changes - Finished Product -Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue	03/10/23
Vet - F.II.a.3 b) 1.	VRA-S - Vet - F.II.a.3 b) 1. - b) Other excipients 1. Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the veterinary medicinal product - F.II.a.3 b) 1. Quality Changes - Finished Product - Description and composition - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the veterinary medicinal product	03/10/23
Vet - B3 r)	VNRA - Vet - B3 r) - r) Deletion of pack size(s) of the finished product - B3 r) Changes to the quality part of the dossier: Deletion of pack size(s) of the finished product	29/09/23
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	28/09/23

	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	
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	29/06/23