

VPA10803/005/001

Malaseb shampoo for dogs and cats

Variation	Summary	Date
Vet - B47 b)	VNRA - Vet - B47 b) - b) Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - B47 b) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	22/12/23
Vet - F.II.c.1 z)	VRA-R - Vet - F.II.c.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.c.1 z) Quality Changes - Finished Product -Control of excipients-Change in the specification parameters and/or limits of an excipient - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	26/07/23
Vet - B43	VNRA - Vet - B43 - Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible - B43 Changes to the quality part of the dossier: Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible	18/04/23
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	03/08/22
B.II.d.2.a	IA - B.II.d.2.a - a) Minor changes to an approved test procedure - B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/02/22