VPA10815/043/001

Modulis 100 mg/ml oral solution for dogs

Variation	Summary	Date
Vet - F.II.f.1 z)	VRA-R - Vet - F.II.f.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.f.1 z) Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	17/10/23
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	21/12/22
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	21/12/22
B.II.d.1.e	II - B.II.d.1.e - e) Change outside the approved specifications limits range - B.II.d.1.e - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	25/07/22
B.II.d.1.g	IB - B.II.d.1.g - g) 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 - B.II.d.1.g - 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	25/07/22
B.II.d.1.g	IB - B.II.d.1.g - g) 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 - B.II.d.1.g - 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	25/07/22