VPA10815/010/001

Altresyn 4 mg/ml oral solution for pigs

Variation	Summary	Date
Vet - F.II.d.2 b)	VRA-R - Vet - F.II.d.2 b) - b) Other changes to a test procedure (including replacement or addition) - F.II.d.2 b) Quality Changes - Finished Product -Control of finished product - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	21/01/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	11/10/24
Vet - I.III.1	VRA-E - Vet - I.III.1 - a) Change or addition of target species - I.III.1 a) Changes of active substance(s), strength, pharmaceutical form, route of administration or food producing target species - Other changes specific to veterinary medicinal products to be administered to food-producing animals - Change or addition of target species	11/10/24
Vet - F.I.d.1 c)	VRA-R - Vet - F.I.d.1 c) - c) Extension or introduction of a re-test period/storage period supported by real time data - F.I.d.1 c) Quality Changes - Active Substance - Stability -Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Extension or introduction of a re-test period/storage period supported by real time data	04/03/24
Vet - F.I.a.1 a)	VRA-S - Vet - F.I.a.1 a) - a) Introduction of a manufacturer of the active substance supported by an ASMF - F.I.a.1 a) - Quality Changes - Active Substance - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF	04/03/24
Vet - F.I.a.1 a)	VRA-S - Vet - F.I.a.1 a) - a) Introduction of a manufacturer of	18/12/23

	the active substance supported by an ASMF - F.I.a.1 a) - Quality Changes - Active Substance - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Introduction of a manufacturer of the active substance supported by an ASMF	
B.I.a.3.a	IA - B.I.a.3.a - a) Up to 10-fold increase compared to the originally approved batch size - B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size	05/05/22
B.I.a.1.a	IB - B.I.a.1.a - a) The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	05/05/22
B.I.a.3.a	IA - B.I.a.3.a - a) Up to 10-fold increase compared to the originally approved batch size - B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size	02/03/22