

VPA22020/037/001

Flubendazole Elanco 50 mg/g oral powder for pigs

Variation	Summary	Date
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	20/10/23
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	25/04/23
B.II.b.1.a	IAin - B.II.b.1.a - a) Secondary packaging site - B.II.b.1.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site	28/02/22
B.II.d.1.d	IA - B.II.d.1.d - d) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) - B.II.d.1.d - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)	28/02/22
B.II.b.2.c.1	IAin - B.II.b.2.c.1 - 1. Not including batch control/testing - B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	28/02/22
B.II.b.2.a	IA - B.II.b.2.a - a) Replacement or addition of a site where batch control/testing takes place - B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch	28/02/22

	control/testing takes place	
B.II.b.2.a	IA - B.II.b.2.a - a) Replacement or addition of a site where batch control/testing takes place - B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place	28/02/22
B.II.b.2.a	IA - B.II.b.2.a - a) Replacement or addition of a site where batch control/testing takes place - B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place	28/02/22
B.II.b.1.b	IAin - B.II.b.1.b - b) Primary packaging site - B.II.b.1.b - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site	28/02/22
B.II.b.1.e	IB - B.II.b.1.e - e) Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products - B.II.b.1.e - 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 nonsterile medicinal products	28/02/22