

VPA22020/048/005

Advantix Spot-on solution for dogs over 40 kg up to 60 kg

Variation	Summary	Date
B.I.b.2.a	IA - B.I.b.2.a - a) Minor changes to an approved test procedure - B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure	30/06/22
B.I.b.1.z	IB - B.I.b.1.z - z Other variation - B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other variation	30/06/22
B.I.b.1.d	IA - B.I.b.1.d - d) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	30/06/22
B.I.b.1.c	IA - B.I.b.1.c - c) Addition of a new specification parameter to the specification with its corresponding test method - B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method	30/06/22
B.I.b.1.b	IA - B.I.b.1.b - b) Tightening of specification limits - B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits	30/06/22
B.I.a.2.e	IB - B.I.a.2.e - e) Minor change to the restricted part of an Active Substance Master File - B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	30/06/22
A.7	IA - A.7 - A.7 Deletion of manufacturing sites 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, reagent or excipient (when mentioned in the dossier)* - A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished	30/06/22

	product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*	
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