VPA10387/046/001

Orbenin Extra Dry Cow 600 mg Intramammary Suspension

Variation	Summary	Date
Vet - F.I.a.2 d)	VRA-S - Vet - F.I.a.2 d) - d) Minor change to the restricted part of an Active Substance Master File - F.I.a.2 d) 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	09/04/24
Vet - F.I.b.1 z)	VRA-S - Vet - F.I.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.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 changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	09/04/24
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)	07/12/23
Vet - B3 d)	VNRA - Vet - B3 d) - d) Deletion of a non-significant specification parameter (active substance, starting material, intermediate - B3 d) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance; — a starting material; —an intermediate or reagent used in the manufacturing process of the active substance	07/12/23
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)	07/12/23
Vet - B3 d)	VNRA - Vet - B3 d) - d) Deletion of a non-significant	07/12/23

	specification parameter (active substance, starting material, intermediate - B3 d) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance; — a starting material; —an intermediate or reagent used in the manufacturing process of the active substance	
Vet - F.I.b.1 z)	VRA-S - Vet - F.I.b.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.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 changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	07/12/23
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier - F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	07/12/23
B.II.b.4.d	II - B.II.b.4.d - d) The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes - B.II.b.4.d - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	27/09/22
B.II.d.2.d	IB - B.II.d.2.d - d) Other changes to a test procedure (including replacement or addition) - B.II.d.2.d - 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)	27/09/22
B.II.d.2.b	IA - B.II.d.2.b - b) Deletion of a test procedure if an alternative method is already authorised - B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	27/09/22
B.II.d.2.b	IA - B.II.d.2.b - b) Deletion of a test procedure if an alternative method is already authorised - B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	27/09/22
B.II.d.2.b	IA - B.II.d.2.b - b) Deletion of a test procedure if an alternative method is already authorised - B.II.d.2.b - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	27/09/22
B.II.d.1.a	IA - B.II.d.1.a - a) Tightening of specification limits - B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or	27/09/22

	limits of the finished product - Tightening of specification limits	
B.II.d.1.a	IA - B.II.d.1.a - a) Tightening of specification limits - B.II.d.1.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	27/09/22
B.II.d.1.z	IB - B.II.d.1.z - z Other variation - B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other variation	27/09/22
B.II.d.1.z	IB - B.II.d.1.z - z Other variation - B.II.d.1.z - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Other variation	27/09/22
B.II.d.1.c	IA - B.II.d.1.c - c) Addition of a new specification parameter to the specification with its corresponding test method - B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	27/09/22
B.II.d.1.c	IA - B.II.d.1.c - c) Addition of a new specification parameter to the specification with its corresponding test method - B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	27/09/22
B.II.d.1.c	IB - B.II.d.1.c - c) Addition of a new specification parameter to the specification with its corresponding test method - B.II.d.1.c - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	27/09/22