VPA10387/074/001

Synulox Palatable Tablets 50 mg

Variation	Summary	Date
Vet - F.II.f.1 a) 2.	VRA-R - Vet - F.II.f.1 a) 2. - a) Extension of the shelf life of the finished product 2. After first opening (supported by real time data) - F.II.f.1 a) 2. Quality Changes -Stability - Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - After first opening (supported by real time data)	10/06/25
Vet - F.II.b.3 z)	VRA-R - Vet - F.II.b.3 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.II.b.3 z) Quality Changes - Finished Product -Manufacture - Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	10/06/25
Vet - F.V.b 1. c)	VRA-S - Vet - F.V.b 1. c) - c) Harmonisation of the quality dossier for the same purely national products and/or the same products approved in MR/DC procedures which are owned by the same MAH not participating in a former union interest referral procedure or SPC harmonisation procedure - F.V.b 1. c) Quality Changes - Changes to a marketing authorisation resulting from other regulatory procedures - Harmonisation of the quality dossier - Harmonisation of the quality dossier for the same purely national products and/or the same products approved in MR/DC procedures which are owned by the same MAH not participating in a former union interest referral procedure or SPC harmonisation procedure	10/06/25
Vet - B3 b)	VNRA - Vet - B3 b) - b) Deletion of a manufacturing process for the active substance or the finished product, including an intermediate used in the manufacture of the finished product when an alternative is already approved - B3 b) Changes to the quality part of the dossier: Deletion of a manufacturing process for the active substance or the finished product, including an intermediate used in the manufacture of the finished product when an alternative is already approved	31/01/23