VPA10996/127/002

Vivitonin 100 mg film-coated tablets

Variation	Summary	Date
Vet - C6	VNRA - Vet - C6 - - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex	17/02/26
Vet - F.II.d.1 z)	VRA-R - Vet - F.II.d.1 z) - - Vet - F.II.d.1 z) - Change in the specification parameters and/or limits of the finished product - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	30/10/25
Vet - F.II.a.1 z)	VRA-R - Vet - F.II.a.1 z) - - Vet - F.II.a.1 z) - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	30/10/25
Vet - B22	VNRA - Vet - B22 - - Vet - B22 - Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	26/08/25
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	25/03/25
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	10/02/25
Vet - B35 a)	VNRA - Vet - B35 a) - a) Tightening of specification limits - B35 a) Changes to the quality part of the dossier: Change in the specification parameters or limits of the immediate packaging of the finished product: — tightening of specification limits	08/08/24
Vet - B3 g)	VNRA - Vet - B3 g) - g) Deletion of a non-significant specification parameter (packaging) - B3 g) Changes to the quality part of the dossier: Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product	08/08/24
Vet - B35 b)	VNRA - Vet - B35 b) - b) Addition of a new specification parameter to the specification with its corresponding test method - B35 b) Changes to the quality part of the dossier: Change in the	08/08/24

	specification parameters or limits of the immediate packaging of the finished product: — addition of a new specification parameter to the specification with its corresponding test method	
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	08/08/24
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	04/07/24
Vet - B12 a)	VNRA - Vet - B12 a) - a) Minor changes to an approved test procedure (active, finished product, packaging, measuirng device) - B12 a) Changes to the quality part of the dossier: Minor changes — to an approved test procedure — for active substance; — for the finished product; —for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	18/06/24
Vet - B30 a)	VNRA - Vet - B30 a) - a) Tightening of specification limits - B30 a) Changes to the quality part of the dossier: Change in the specification parameters or limits of the finished product: — tightening of specification limits	23/01/24
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	24/10/23
Vet - F.I.b.2 b)	VRA-R - Vet - F.I.b.2 b) - b) Other changes to a test procedure (including replacement or addition) for the active substance - F.I.b.2 b) 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 - Other changes to a test procedure (including replacement or addition) for the active	17/04/23

	substance	