

VPA10988/052/001

**Stabox 5g Premix for medicated feeding stuff**

Variation	Summary	Date
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	27/11/23
B.II.f.1.d	IB - B.II.f.1.d - d) Change in storage conditions of the finished product or the diluted/reconstituted product - B.II.f.1.d - QUALITY CHANGES - FINISHED PRODUCT - Stability - Change in the shelf-life or storage conditions of the finished product - Change in storage conditions of the finished product or the diluted/reconstituted product	12/07/22
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	12/07/22
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	12/07/22
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	12/07/22
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	12/07/22
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)	12/07/22
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)	12/07/22