

VPA22693/020/001

Kilo-mec 1% Solution for Injection

Variation	Summary	Date
Vet - B3 e)	VNRA - Vet - B3 e) - e) Deletion of a test procedure - B3 e) Changes to the quality part of the dossier: Deletion of a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance; —for the immediate packaging of the active substance; — for an excipient or the finished product; —for the immediate packaging of the finished product	31/01/24
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	31/01/24
Vet - F.II.e.5 b)	VRA-S - Vet - F.II.e.5 b) - b) Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products. - F.II.e.5 b) Quality Changes - Container closure system -Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products.	17/02/23
Vet - F.II.e.1 b) 2.	VRA-S - Vet - F.II.e.1 b) 2. - b) Change in type of container or addition of a new container 2. Sterile medicinal products and biological/ immunological medicinal products - F.II.e.1 b) 2. Quality Changes - Container closure system - Change in immediate packaging of the finished product - Change in type of container or addition of a new container - Sterile medicinal products and biological/immunological medicinal products	17/02/23