

VPA10976/002/001

Gentaject 10% Solution for Injection for Horses

Variation	Summary	Date
B.II.d.2.a	IA - B.II.d.2.a - a) Minor changes to an approved test procedure - B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/04/22
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	12/04/22
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 limits of the finished product - Tightening of specification limits	12/04/22
B.II.b.3.a	IA - B.II.b.3.a - a) Minor change in the manufacturing process - B.II.b.3.a - 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 - Minor change in the manufacturing process	12/04/22
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	12/04/22