Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911 Fax +44 (0)1932 336618

Post Authorisation Assessments

Norodine Granules

Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. 14 November 2016 Submission of an updated certificate of suitability. OP January 2014 Change to the specification parameters for the finished product. Variation to update Ph. Eur. Certificates of Suitability for already approved Active Substance Manufacturers. OP February 2009 Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. OP October 2008 Deletion of a Manufacturer. Penewal. OP May 2008 Variation to updated a Certificate of Suitability. Addition of an Active Substance Manufacturer. Addition of a Manufacturer/Assembler. Horse Passport Variation. Addition of a Manufacturer. Addition of an Active Substance Manufacturer. Addition of an Assembler of Dosage Form. Addition of an Assembler of Dosage Form. Addition of an Active Substance Manufacturer.		00.1.1.0040	01 0.000/ (
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