

What is the status of the monograph on Gonadotrophin, equine serum, for veterinary use (0719)?



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Answer:

The monograph on *Gonadotrophin, equine serum, for veterinary use (0719)* was elaborated in the 1980s and published in the 2nd Edition of the European Pharmacopoeia (Ph. Eur.), Fascicule 15, in 1991. The estimation of potency of preparations covered by this monograph relied on comparative analyses performed with the World Health Organization (WHO) International Standard (IS) for equine serum gonadotrophin.

Since the stocks of the IS have been exhausted and not available from the producer (NIBSC) since 2019, the monograph could no longer be applied. As a result, the Ph. Eur. Commission decided at its 170th plenary session in June 2021 to suspend the monograph, and it has not been included in the Ph. Eur. since Supplement 10.8. The monograph nonetheless remains on the Ph. Eur. work programme until a final decision on its fate can be taken. Any further decisions on this topic will be published on the [Ph. Eur. news page](#) on the EDQM website.

Since the IS for equine serum gonadotrophin and the corresponding International Unit are under the remit of the WHO, we advise that any questions in this respect be addressed directly to the WHO.