The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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CPMP/BWP/1952/98

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

POSITION STATEMENT ON POLYSORBATE 80

Provided that polysorbate complies with the European Pharmacopoeia (Ph.Eur.) Monograph requirements, no additional virus inactivation/ validation studies are necessary when switching from polysorbate 80 of animal origin to the one of vegetable origin. Experimental data presented to the BWP indicated that the switch from polysorbate of animal origin to the one of vegetable origin did not affect the efficiency of the virus inactivation in the SD treatment.

The question whether, in the polysorbate monograph, the physico-chemical aspects linked to the solubilisation of the lipids need to be further elaborated, had been referred to the Ph.Eur.

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