VALIDATION OF VIRUS REMOVAL/INACTIVATION PROCEDURES: CHOICE OF VIRUSES

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Additional Notes	**Data on the validation of processes for the removal or inactivation of viruses are rapidly accumulating. Validation studies should therefore be reviewed and updated if necessary at intervals to ensure that they are consistent with current scientific knowledge.**

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Where possible studies should be performed with species of viruses which may be present in plasma, such as HIV. In some cases this will not be possible. For example hepatitis C virus (HepCV) cannot be grown or assayed readily, so that model viruses must be used. The model virus chosen should be as close in its relevant properties to HepCV as possible. In the past, togaviruses such as Sindbis virus, flaviviruses such as yellow fever virus and pestiviruses such as bovine viral diarrhoea virus have been used as models for HepCV. All have properties in common with HepCV and the results have generally been consistent with the safety of the product in clinical use. Further data on the behaviour of the viruses are needed to identify the most appropriate model.

Hepatitis A virus is a non-enveloped virus of the picornavirus family which is believed to have been transmitted by clotting factors. Hepatitis A virus should be used whenever possible as it is thought to be significantly more hardy than other picornaviruses. However plasma pools can contain neutralising antibodies which may make validation studies difficult. In addition, hepatitis A virus may be technically demanding to grow and assay. Alternative viruses such as EMC or Theiler's virus or the use of pools screened for the absence of antibodies to HAV in validation studies may be considered where relevant. The choice of model viruses for hepatitis A, if any, will become clear with further studies.