Heat Treatment As A Risk Management Tool

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ISIA members are often asked about the potential for the use of heat treatment as a risk mitigation step in the reduction of viral load in serum. The ISIA has previously been responsible for the generation of a series of papers detailing various aspects of treatment of serum which are available on the ISIA website [1 6].

Heat Inactivation of serum has been in practice for many years and is an effective treatment for the inactivation of complement in all types of sera. The standard protocol for heat inactivation is the immersion of finished, bottled serum in a 56°C water bath. Bottles must be agitated and allowed to reach 56°C for 30 minutes. [7] The nature of this protocol means that there is inherent variability in the treatment, as not all bottles will be exposed to the same conditions for the same time. It is also possible to heat inactivate serum in bulk, prior to bottling.

To understand the potential efficacy of heat inactivation as a risk mitigation step for the reduction of viral load, Dr Raymond Nims of RMC Pharmaceutical Solutions, Inc. performed an extensive literature review comparing irradiation to heat inactivation. [8-11].

The results are shown in the attached Table 1. The data shown demonstrates that while heat treatment does have a slight impact on the viral burden, gamma irradiation has a significantly increased action on a wide variety of viruses. The ISIA believes that while heat treatment is suitable for the reduction of complement in serum, this method is not appropriate as a routine risk mitigation step for the reduction of viral load. It should be noted that there may be exceptions depending on low virus levels and the type of virus present– further studies should be conducted to evaluate the presence or absence of viral infectivity after heat-Inactivation if this method is utilized.[12]

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Table I. Literature review comparing gamma Irradiation and heat inactivation of different viruses.

Virus	Family	Gamma irradiation (Log 10 reduction per 25 kGy)	Heat (56°C, 30 minutes)
Enveloped (large sized)			
Schmallenberg virus	bunyavirus	4.0	2.6
Cache Valley virus	bunyavirus	4.0	2.6
Infectious bovine rhinotracheitis virus	herpesvirus	7.8	4.1
Bovine coronavirus	coronavirus	>12	6.2
Bovine leukosis virus	retrovirus	3.3	21
Rabies virus	rhabdovirus	8.5	22
Vesicular stomatis virus	rhabdovirus	8.5	22
Parainfluenza type 3	paramyxovirus	5.2	9.7
Bovine respiratory syncytial virus	paramyxovirus	5.2	9.7
Enveloped (medium sized)			
Bovine viral diarrhea virus	flavivirus	5.0	6.0
West Nile virus	flavivirus	5.0	6.0
Non-enveloped (large sized)			
Bovine adenovirus	adenovirus	5.1	2.1
Non-enveloped (medium sized)			
Reovirus	reovirus	4.9	**<1**
Bluetongue virus	reovirus	**3.0**	<1
Bovine rotavirus	reovirus	3.9	**2**
Epizootic hemorrhagic disease virus	reovirus	3.9	<1
Non-enveloped (small sized)			
Bovine polyomavirus	polyomavirus	1.4	0.5
Seneca Valley virus	picornavirus	4.8	3.0
Foot and mouth disease virus	picornavirus	4.8	**3.0**
Vesivirus 2117	calicivirus	5.0	5.9
Bovine parvovirus	parvovirus	1.4	**<1.0**

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