

**VALIDATION CHECK LIST FOR AN ANIMAL TEST CERTIFICATE FOR
IMMUNOLOGICAL BIOLOGICAL PRODUCTS**

Product Name:	Company:
Application Type:	Date of Validation:
Application Number:	
SP Number:	

PAGE	PRESENTATION	COMMENTS
	Indexing/Sectioning Pagination Legibility Binding	

I A Administrative details		
	Product name and active ingredients Payment status Source Qualitative and quantitative composition Name and address of applicant Name and address of sites of testing Manufacturing site description and authorisation certificate	
IB Trial Protocol		
	<p>Details of any earlier ATC(s) concerning this product</p> <p>Details of any UK marketing authorisation or product licence applied for or granted</p> <p>Details of any applications concerning his product made in other countries</p> <p>Draft label and product literature to be used for the test</p> <p>Description and/or test protocol to include:</p> <ul style="list-style-type: none"> - Nature and Purpose of Test - Species of Animal - Maximum Number of Animals - Selection Criteria - Safety monitoring - User precautions - Disposal of unused product - Disposal of test animals - Withdrawal periods - Method of Administration/Dose Rate - Test supervisor - Test site details - Welfare 	

II QUALITY		
II A Qualitative And Quantitative Particulars		
	Table of qualitative and quantitative particulars Containers and closures Development pharmaceuticals	

II B	Method Of Preparation
	Flow chart and description of manufacture Inactivation Kinetics Table of blending details
II C	Starting Materials (Specification and Certificate of Analysis)
	Listed in a Pharmacopoeia Not listed in a Pharmacopoeia (a) Biological origin Passage history and source, Description and preparation, Testing of master and working seeds, Storage conditions, Identification and characteristics, Processing and testing, Genetic engineering details (b) Non-biological origin (c) Media Annex with certificate of analysis for each substance purchased.
II D	TSE Certificates, Declaration and Format
	Risk assessment Certificates Declaration Format Table
II E	In-Process Control Tests
	Flow Chart Tests Batch to Batch consistency
II F	Control Tests On The Finished Product
III SAFETY	
III A	Laboratory Tests
	Safety of administration of one dose Safety of one administration of an overdose Special requirements for live vaccines (a) Spread of the vaccine strain (b) Dissemination in the vaccinated animal (c) Reversion to virulence of attenuated vaccines Study of residues Interactions Any known interactions with other products
III D	Ecotoxicity
	Phase I with conclusion
V A	General Conclusions
V B	Bibliographic References

V1 Type A Report (Sar)
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NOTES: