



Microbiological
Validation
Services Ltd

Microbiological Validation Services Ltd VDMAX Submission Form

CUSTOMER NAME:		PURCHASE ORDER NO:	
NUMBER OF SAMPLES SUBMITTED:		SUBMITTED BY:	
DESCRIPTION OF SAMPLES:			
Please select one of the 3 options below:			
1. JUSTIFICATION / SUBSTANTIATION FOR MULTIPLE BATCHES OF PRODUCT YES / NO			
NOTE: Follows section 9.2 of ISO 11137-2 'Procedure for Method VDmax25 for multiple production batches' Requires at least 10 non-sterile samples from each of 3 production batches, 50 samples in total)			
2. RE-JUSTIFICATION / AUDIT OF DOSE SUBSTANTIATED IN ORIGINAL EXERCISE YES / NO			
NOTE: Follows section 10.3 of ISO 11137-2 Procedure for auditing a sterilization dose substantiated using Method VDmax25 or VDmax15'. Requires at least 30 non-sterile samples from a single production batch.			
IF OPTION 2 IS SELECTED PLEASE PROVIDE REFERENCE OF ORIGINAL JUSTIFICATION / SUBSTANTIATION:			
3. SINGLE PRODUCTION BATCH VALIDATION YES / NO			
NOTE: Follows Section 9.3 of ISO 11137-2 'Procedure for Method VDmax25 for a single production batch'. Requires at least 30 non-sterile samples from a single production batch. Valid only for the sterilization of the batch of product submitted.			
IF A DOSE OTHER THAN 25kGy IS REQUIRED, PLEASE SPECIFY:			
PRODUCT REFERENCE:		BATCH NUMBER(S);	
ANY OTHER INFORMATION:			
COMMENTS:			
SIGNED:		DATE:	

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