Microbiological Validation Services Ltd

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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 REPORT 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:

IF PRODUCT IS FOR ANY OTHER METHOD THAN GAMMA, PLEASE SPECIFY:

PRODUCT REFERENCE:	BATCH NUMBER(S);
ANY OTHER INFORMATION:	
COMMENTS:	
SIGNED:	DATE:

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