Microbiological
Validation
Services Ltd

Microbiological Validation Services Ltd
Method 1 Submission Form

CUSTOMER NAME:	PURCHASE ORDER NO:
NUMBER OF SAMPLES SUBMITTED:	
DESCRIPTION OF SAMPLES:	
IF PRODUCT IS FOR ANY OTHER METHOD THAN GAMMA, PLEASE SPECIFY:	
Please select one of the 3 options below:	
1. JUSTIFICATION / SUBSTANTIATION FOR MULTIPLE BATCHES OF PRODUCT **YES / NO** NOTE: Follows ISO 11137-2 'Procedure for Method 1 Dose Setting for multiple production batches'. Requires non-sterile samples, at least 10 samples from each of 3 production batches for bioburden testing and 100 samples for tests of sterility, 130 samples in total.	
2. RE-JUSTIFICATION / AUDIT OF DOSE SUBSTANTIATED IN ORIGINAL EXERCISE **YES / NO** **TARGET DOSE (kGy):** NOTE: Follows ISO 11137-2 'Procedure for auditing a sterilization dose substantiated using Method 1 Dose Audit'. Requires non-sterile samples, at least 10 samples from a single production batch for bioburden testing and 100 samples for tests of sterility, 110 samples in total.	
IF OPTION 2 IS SELECTED PLEASE PROVIDE REPORT REFERENCE OF ORIGINAL JUSTIFICATION / SUBSTANTIATION: *If the original dose setting was carried out by a different laboratory, the full report must be provided before work commences.*	
3. SINGLE PRODUCTION BATCH VALIDATION **YES / NO** NOTE: Follows ISO 11137-2 'Procedure for Method 1 Dose Setting for a single production batch'. Requires non-sterile samples, at least 10 samples from a single production batch for bioburden testing and 100 samples for tests of sterility, 110 samples in total. **Valid only for the sterilization of the batch of product submitted.**	
PRODUCT REFERENCE:	BATCH NUMBER(S);
FOR OFFICE USE ONLY:	
ANY OTHER INFORMATION:	
CORRECTION FACTOR:	STASIS REQUIRED: BIOBURDEN / STERILITY
DOSE REQUIRED:	DOSE RANGE:
SIGNED:	DATE:

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