BACTERIA ENDOTOXIN TEST (BET) VALIDATION

Product Name/Protocol No.	
Method Used	Photometric - Turbimetric / Chromogenic (Kinetic / End-Point)

Subject	Acceptance Criteria	Details Provided by Company	Comments
Protocol of Analysis			
CoA	- check endotoxin level & pH - Endotoxin level in USP/BP/EP - Provide the CoA for lysate & endotoxin (parallel batch)		
List of apparatus and reagents	- Depyrogenation of glasswares - List of reagents used - LAL water/WFI, endotoxin, Lysate, pH adjustor (buffer/acid/base)		
Preparation of Reagents	- Lysate - Endotoxin		
Preparation of Endotoxin Standard	- At least 3 concentrations - How the serial dilution performed		
Preparation of Sample	- Must be specific to product - Dilution, pH adjustment, additives (e.g. pyrosperse, MgCl2 etc)		
MVD calculation	- Real calculation, not formula $MVD = \dfrac{EL \times Conc}{\lambda}$		
ELC Calculation (if applicable)	- Real calculation, not formula $ELC = K/D \times Conc$		
Validation - method (can be in Protocol of Analysis or in the Validation section) and raw data			
i. Preparatory Testing			
Criteria for the standard curve	- 3 endotoxin concentration to generate standard curve - 3 replicates for each concentration		

	-correlation coefficient (r) must be ≥ 0.98 (linear graph must be demonstrated) - Y intercept must be within 2.5 - 3.5 - Slope of std curve must be within 0.400 - 0.100		
Test for interfering factors	PPC Recovery must be between 50% - 200% Sample must meet the limit specified		