

CHECKLIST FOR BACTERIAL ENDOTOXIN TEST (BET)

Validation test		
1.	Confirmation of Labeled Lysate Sensitivity (Gel Clot) / Standard Curve (Photometric Method)- 1 Batch of Endotoxin	<p style="text-align: center;">Method</p> <p>Gel Clot Method must have these following informations:-</p> <ul style="list-style-type: none"> - 1 batch of lysate - At least 4 concentration of standard endotoxin (2 λ, λ, 0.5 λ, 0.25 λ) - 4 replicates - Geometric Mean of End Point= 0.5 λ - 2 λ <p>Photometric Method: For the generation of standard curve applicant must provide the following information*:</p> <ul style="list-style-type: none"> - 3 endotoxin concentration to generate standard curve - 3 replicates for each concentration - correlation coefficient (r) must be ≥ 0.98 (linear graph must be demonstrated)
		<p style="text-align: center;">Result (raw data)</p> <p>Gel Clot:</p> <ul style="list-style-type: none"> - Geometric Mean of End Point= 0.5 λ - 2 λ <p>Photometric:</p> <ul style="list-style-type: none"> - Standard Curve following the criteria set in Method.
2.	Test for Interfering Factor (Gel Clot/ Photometric Method)- 3 Batches of finished product	<p style="text-align: center;">Method</p> <p>Gel Clot Method must have these following informations:-</p> <ul style="list-style-type: none"> - Detailed method for Test for Interfering Factor - 3 batches of finished product - A: sample only - 4 replicates - B: sample + endotoxin (2λ or 4 different λ concentration)- 4 replicates - C: LAL water + endotoxin (4 different λ concentration) - 2 replicates - D: LAL water only - 2 replicates <p>Photometric Method:</p> <ul style="list-style-type: none"> - PPC Recovery must be between 50% - 200%
		<p style="text-align: center;">Result (raw data)</p> <p>Gel Clot:</p> <ul style="list-style-type: none"> - Raw data following the criteria set in Method for 3 batches of finished product. - A and D must be negative - Geometric Mean of End Point= 0.5 λ - 2 λ <p>Photometric:</p> <ul style="list-style-type: none"> - PPC Recovery between 50% - 200%
3.	MVD Calculation & ELC Calculation (if applicable) (Gel Clot/Photometric Method)	<p style="text-align: center;">Method</p> <ul style="list-style-type: none"> - Calculation of MVD or ELC (if applicable) (Formula)
		<p style="text-align: center;">Result (raw data)</p> <ul style="list-style-type: none"> - Actual calculation - Product specific

Routine Test		
1.	COA for Lysate and Endotoxin (Gel Clot/ Photometric Method)	
2.	List of Apparatus and Reagents (Gel Clot/ Photometric Method)	
3.	Preparation of Reagents, Endotoxin Standard and Sample. (Gel Clot/ Photometric Method)	<p style="text-align: center;">Method</p> <ul style="list-style-type: none"> - Detailed procedure for preparation of reagent, endotoxin standard and sample - Steps for dilution wherever applicable
		<p style="text-align: center;">Result (raw data)</p> <ul style="list-style-type: none"> - Actual dilution records.
4.	MVD Calculation & ELC Calculation (if applicable) (Gel Clot/Photometric Method)	<p style="text-align: center;">Method</p> <ul style="list-style-type: none"> - Calculation of MVD or ELC (if applicable) (Formula)
		<p style="text-align: center;">Result (raw data)</p> <ul style="list-style-type: none"> - Actual calculation - Product specific
5.	Limit Test /Semi quantitative Test (Gel Clot/ Photometric Method)	<p style="text-align: center;">Method</p> <p>Gel Clot Method must have these following informations:-</p> <ul style="list-style-type: none"> - Detailed procedure on how to perform routine bacteria endotoxin testing. - 3 batches of finished product - A: sample only – 2 replicates - B: sample + endotoxin (2λ concentration) – 2 replicates - C: LAL water + endotoxin (2λ concentration) – 2 replicates - D: LAL water only – 2 replicates - A and D must be negative - B and C must be positive <p>Photometric Method:</p> <ul style="list-style-type: none"> - Detailed procedure on how to perform routine bacteria endotoxin testing. - Sample must meet limit specified and PPC Recovery must be between 50% - 200%
		<p style="text-align: center;">Result (raw data)</p> <p>Gel Clot:</p> <ul style="list-style-type: none"> - Raw data following the criteria set in Method for 3 batches of finished product. - A and D must be negative - B and C must be positive <p>Photometric Method</p> <ul style="list-style-type: none"> - Sample meet the limit specified. - PPC Recovery between 50% - 200%

Updated : 5th September 2017