



Maximum Valid Dilution & Endotoxin Limit Calculations

(Ref. MICLAB 105 & MICLAB 085)

Maximum Valid Dilution (MVD) and Endotoxin Limits for Sterile finished Products Tested by LAL Gel Clot and KCA Test methods

Product:	
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D = Maximum human dose/Kg	mg/Kg
	ml/Kg

Potency of Product	mg/ml
This is not required if the dose is expressed in ml/kg	

λ = Sensitivity of Lysate	EU/ml
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K = 5.0 EU/Kg for parenterals except intrathecal drugs where k = 0.2
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Endotoxin Limit	EU/ml
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$$\text{MVD} = \frac{\text{Endotoxin Limit}}{\lambda}$$

λ

Therefore: MVD for Product = _____

Calculation for Endotoxin Limit if required

$$\text{Endotoxin Limit} = \frac{K \times \text{Potency}}{D}$$

Therefore: Endotoxin Limit for Product = _____