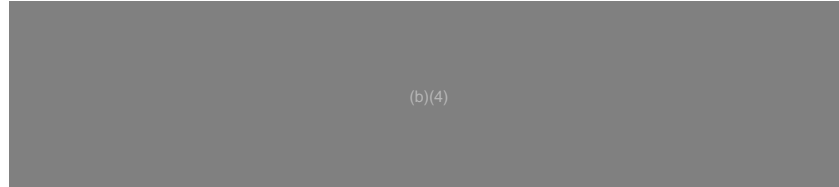


Table 2.3-2 Manufacturers [Kamada-API]

Company	Responsibility
Kamada Ltd. Beit Kama MP Negev 85325 Israel Head Office: Kamada Ltd. 7 Sapir St. Kiryat Weizmann, Science Park PO Box 4081 Ness-Ziona 74036 Israel	Manufacture and Quality Control of DS Batch release Stability testing
(b)(4)	

Table 2.3-2 Manufacturers [Kamada-API] (Cont.)



(b)(4)

Pages 3 through 6 redacted for the following reasons:

(b)(4)

Table 2.3-33 Drug Product Specifications and Release Tests

Test	Specification	Analytical procedure		
Appearance	The solution is clear and colorless to yellow-green. May contain a few particles.	Visual inspection		
Identification				
(b)(4)	(b)(4)			
Potency				
Total Active API Content	(b)(4)			
Active API Content				
Specific Activity				
Excipients				
Sodium				
Chloride (as NaCl)				
Phosphate				
Purity and impurities				
(b)(4)				
Residual TnBP ¹				
Residual Tween 80 ¹				
(b)(4)				
Safety				
Bacterial Endotoxin			(b)(4)	(b)(4) technique
Pyrogenicity	Pass	Rabbit pyrogen test		
Sterility	Pass	Membrane filtration		
General Safety Test	Meets Requirements	21 CFR 610.11		
General Tests				
pH	(b)(4)			
Extractable volume				

¹ (b)(4)

² As per (b)(4), in case of dispute, the final decision is based on the (b)(4) technique

Table 2.3-28 Composition of 50 ml Kamada-API Solution for Infusion

Starting Materials	Concentration Unit and/or Percentage w/v	Function	Reference
API (Alpha- 1- Proteinase Inhibitor)	(b)(4)	Active substance	Kamada specifications 3.2.P.5.1
(b)(4) Sodium Phosphate (b)(4)		pH Buffer	(b)(4)
Sodium Chloride		Electrolyte concentration adjustment	
WFI		Solvent	