

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 2.3-30 Manufacturers [Kamada-API]

Company	Responsibility
Kamada Ltd.	Manufacture and Quality Control of DP
Beit Kama	Labeling and packaging
MP Negev 85325	Lot release
Israel	Stability testing.

(b)(4)

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

(b)(4)	
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Table 2.3-30 Manufacturers [Kamada-API]

Company	Responsibility
Kamada Ltd.	Manufacture and Quality Control of DP
Beit Kama	Labeling and packaging
MP Negev 85325	Lot release
Israel	Stability testing.
(b)(4)	

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)	2 %	Active substance	Kamada specifications 3.2.P.5.1
(b)(4) Sodium Phosphate (b)(4)	(b)(4)	pH Buffer	current (b)(4) monograph 3.2.P.4.1
Sodium Chloride	(b)(4)	Electrolyte concentration adjustment	current (b)(4) monograph 3.2.P.4.1
WFI	Qs ad 50ml	Solvent	current (b)(4) monograph 3.2.P.4.1

Table P.5.1-1 Kamada-API 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		
Active API Content		
Specific Activity		
Excipients		
Sodium Chloride (as NaCl)		
Phosphate		
Purity and Impurities		
(b)(4)		
(b)(4)		
Residual TnBP ¹		
Residual Tween 80 ¹		
(b)(4)		
Safety		
Bacterial Endotoxin	(b)(4)	(b)(4)
Pyrogenicity	Pass	
Sterility	Pass	Membrane filtration
General Safety Test	Meets Requirements	Mice and guinea pigs toxicity (21 CFR 610.11)
General tests		
pH	(b)(4)	(b)(4)
Extractable Volume		

¹

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

Pages 7 through 27 redacted for the following reasons:

(b)(4)

Table S.2.6-1 Overview of API Pilot Runs Used in the Preclinical Studies

Lot #	Date of Manuf.	Type of production, Weight of starting material	Pre clinical study	Formulation (fill size)
(b)(4)	May 2000	Pilot, (b)(4)	Acute Toxicity Study in Sprague-Dawley Rats Acute Toxicity Study in New Zealand White (NZW) Rabbits	(b)(4)
	May 2000	Pilot, (b)(4)	Acute Toxicity Study in Sprague-Dawley Rats Acute Toxicity Study in NZW Rabbits	
	June 2000	Pilot, (b)(4)	Repeated Toxicity In NZW Rabbits	
	Nov 2000	Pilot, (b)(4)	Repeated Toxicity In NZW Rabbits	
	Jan 2002	Full scale, (b)(4)	Pharmacokinetics in Rabbits	
	Oct 2002	Full scale, (b)(4)	Neoantigenicity ²	
	Oct 2003	Full scale, (b)(4)	<i>In-vitro</i> Cytotoxicity Study in (b)(4) cell line (b)(4) Study Using (b)(4) ^M system	

¹ The lots (b)(4) were produced from the same DS batch.

² This study used re-S/D material (intermediate batch # (b)(4) and on the final lot (b)(4) which represents API that had undergone viral reduction by nanofiltration and S/D treatment.

Table S.2.6-2 Overview of API Lots Used in the Clinical Studies vs. Manufacturing Facility Upgrades

Lot #	Date of Manuf.	Phase	(b)(4)
6112006	May 2002	I	Recovered Plasma
First manufacturing facility upgrade (2003)			
6115005	May 2005	II/III	Recovered Plasma
6115006	June 2005	II/III	Recovered Plasma
6116003	March 2006	II/III	Recovered Plasma
6116004	April 2006	II/III	Recovered Plasma
6126004	April 2006	II/III	Recovered Plasma
6116008	Aug 2006	II/III	Recovered Plasma
6116011	Nov 2006	II/III	Recovered Plasma
Second manufacturing facility upgrade (2007)			

Table S.2.6-3 DS Batches and DP Lots Produced and Their Manufacturing Dates.

Starting Material for (b)(4)	Drug Substance		Drug Product	
	Batch no.	Manufacturing Date	Lot no.	Manufacturing Date
Recovered Plasma	(b)(4)			
Source Plasma				

Table P.3.5-15 Traceability of Drug Product Lots Produced for Establishing Lot to Lot Consistency

Study	DP Lot No.	DS Batch No.	Plasma Type
Comparability of Drug Product Manufactured from Source and Recovered Plasma	(b)(4)		
Conformance Protocol: Production of API Drug Product from Source and Recovered Plasma			

Table P.3.5-18 Drug Substance Batches and Drug Product Lots Produced

Study	DS Batch Number	DS Storage Time at 2-8°C (months)	DP Lot Number
Recovered versus Source Plasma Comparability Studies	(b)(4)		
Process Conformance Studies			

Pages 33 through 37 redacted for the following reasons:

(b)(4)