

Client:	Generic Pharmaceuticals, Inc.	Responsible Lab:	Generic Pharmaceuticals, Inc.
Product:	CURE-IT-ALL® for Injection, 50 mg/mL	Storage Condition:	(not stored)
Formulation:	Alpha-1	Storage Time:	Initial
Batch:	Lot 12973	Units Needed:	60
Study:	29833 Stability Protocol	Units Removed:	<input type="text" value="60"/>
LWR Status:	Approved Jan 29, 2008 16:27:35 by Daniel Robinson	Date Removed:	<input type="text" value="Jan 29, 2007"/>

**Appearance Packaging**

Conforms	Units Failed specifications? <input type="checkbox"/>	Precision <input type="checkbox"/>	Specifications Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact
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*Appearance Packaging*

Comments:

Performing Analyst:	<input type="text" value="Kevin Huestis"/>	Notebook Reference:	<input type="text" value="TC001, p. 4"/>
Method Reference:	<input type="text" value="TM001"/>	Date Tested:	<input type="text" value="Jan 29, 2007"/>
		Test Status:	<input type="text" value="Approved"/>

**Appearance Reconstituted**

Conforms	Units Failed specifications? <input type="checkbox"/>	Precision <input type="checkbox"/>	Specifications Clear colorless solution free of visible particulate matter
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*Appearance Powder*

Comments:

Performing Analyst:	<input type="text" value="Kevin Huestis"/>	Notebook Reference:	<input type="text" value="TC001, p. 4"/>
Method Reference:	<input type="text" value="TM001"/>	Date Tested:	<input type="text" value="Jan 29, 2007"/>
		Test Status:	<input type="text" value="Approved"/>

**Assay**

100.0	Units % I.c.	Precision 1 decimal	Specifications lo=90.0, hi=110.0
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*Prolastin*

Comments:

Performing Analyst:	Kevin Huestis	Notebook Reference:	TC001, p. 4
Method Reference:	TM002	Date Tested:	Jan 29, 2007
		Test Status:	Approved

**Moisture**

0.9	Units %	Precision 1 decimal	Specifications hi=2.0
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*Moisture*

Comments:

Performing Analyst:	Kevin Huestis	Notebook Reference:	TC001, p. 4
Method Reference:	TM003	Date Tested:	Jan 29, 2007
		Test Status:	Approved

**pH**

7.0	Units	Precision 1 decimal	Specifications lo=6.6, hi=7.4
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*pH*

Comments:

Performing Analyst:	Kevin Huestis	Notebook Reference:	TC001, p. 4
Method Reference:	TM004	Date Tested:	Jan 29, 2007
		Test Status:	Approved

**Particulate Testing**

259	Units Counts per container	Precision 0 decimal	Specifications hi=6000
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*10 µm*

23	Units Counts per container	Precision 0 decimal	Specifications hi=600
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*25 µm*

Comments:

Performing Analyst:	Daniel Robinson	Notebook Reference:	TC001, p. 5
Method Reference:	USP 788	Date Tested:	Jan 29, 2007
		Test Status:	Approved