

| | | | |
|--------------|---|--------------------|---|
| 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 | Precision | Specifications |
| | Failed specifications? | <input type="checkbox"/> | Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact |

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 | Precision | Specifications |
| | Failed specifications? | <input type="checkbox"/> | Clear colorless solution free of visible particulate matter |

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 | Precision | Specifications |
| | % I.c. | 1 decimal | lo=90.0, hi=110.0 |

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 |
|-----|------------|------------------------|--------------------------|

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 |
|-----|-------|------------------------|----------------------------------|

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 |
|-----|-------------------------------|------------------------|---------------------------|

10 μ m

| | | | |
|----|-------------------------------|------------------------|--------------------------|
| 23 | Units Counts per container | Precision 0 decimal | Specifications hi=600 |
|----|-------------------------------|------------------------|--------------------------|

25 μ m

Comments:

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