

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

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|---------------------------------|---|------------------------------|---|
| Product / Strength: | CURE-IT-ALL® for Injection, 50 mg/mL | Lot # / Mfg. Date: | Lot 12973 / Jan 23, 2007 |
| Mfg. By / Site: | Generic Direct® | Packager / Site: | Generic Direct® |
| Batch Size: | 1,000,000 vials | Packaging Date: | Jan 26, 2007 |
| Purpose of Study: | Production Support | Study Start Date: | Jan 28, 2007 |
| Expiration Date: | TBD | Study Duration: | 36 month |
| Active Ingredient (API): | Aspirin | Container / Supplier: | 50 cc clear vial / Fisher Scientific |
| API Mfg. / Lot# (s): | Sigma - Aldrich / 1234 | Closure / Supplier: | Aluminum Crimp top seal / Fisher Scientific Grey Rubber Induction Seal / Fisher Scientific |
| Test Location(s): | Generic Pharmaceuticals, Inc., Northfield Labs | | |

Stability Condition / Orientation: 25°C ± 2°C/60% RH ± 5% RH

| Specifications | | | Stability Intervals | | | | |
|--|---------|---|---------------------|--------------|-------------------------|-------------------------|------------------|
| Test | Method | Acceptance Criteria | Initial | 1 month | 3 month | 6 month | 12 month |
| Appearance Packaging | TM001 | Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact | Conforms | Conforms | Conforms | Conforms | Pending Approval |
| Appearance Reconstituted - Appearance Powder | TM001 | Clear colorless solution free of visible particulate matter | Conforms | Conforms | Conforms | Conforms | Pending Approval |
| Assay - Prolastin | TM002 | 90.0 to 110.0 % I.c. | 100.0 | 99.9 | 99.1 | 98.7 | Pending Approval |
| Moisture | TM003 | NMT 2.0 % | 0.9 | 1.1 | 1.2 | 1.3 | Pending Approval |
| pH | TM004 | 6.6 to 7.4 | 7.0 | 7.1 | 7.1 | 7.0 | Pending Approval |
| Particulate Testing - 10 µm | USP 788 | NMT 6000 Counts per container | 259 | 499 | 475 | 399 | Pending Approval |
| Particulate Testing - 25 µm | USP 788 | NMT 600 Counts per container | 23 | 24 | 83 | 78 | Pending Approval |
| Micro - Escherichia coli | NF001 | Absent | Absent | Absent | Not Tested per Protocol | Not Tested per Protocol | Absent |
| Micro - Pseudomonas aeruginosa | NF001 | Absent | Absent | Absent | Not Tested per Protocol | Not Tested per Protocol | Absent |
| Micro - Total Aerobic Count | NF001 | Report Results | ND | ND | Not Tested per Protocol | Not Tested per Protocol | ND |
| Test Date(s) | | | Jan 29, 2007 | Feb 28, 2007 | Apr 28, 2007 | Jul 28, 2007 | Jan 29, 2008 |

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

Stability Condition / Orientation: 25°C ± 2°C/60% RH ± 5% RH Inverted

| Specifications | | | Stability Intervals | | | | |
|--|---------|---|---------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Test | Method | Acceptance Criteria | Initial | 1 month | 3 month | 6 month | 12 month |
| Appearance Packaging | TM001 | Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact | Conforms | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| Appearance Reconstituted - Appearance Powder | TM001 | Clear colorless solution free of visible particulate matter | Conforms | Conforms | Conforms | Conforms | Conforms |
| Assay - Prolastin | TM002 | 90.0 to 110.0 % l.c. | 100.0 | 99.8 | 98.6 | 98.7 | 98.2 |
| Moisture | TM003 | NMT 2.0 % | 0.9 | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| pH | TM004 | 6.6 to 7.4 | 7.0 | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| Particulate Testing - 10 µm | USP 788 | NMT 6000 Counts per container | 259 | 3100 | 3200 | 3400 | 3743 |
| Particulate Testing - 25 µm | USP 788 | NMT 600 Counts per container | 23 | 390 | 329 | 324 | 398 |
| Micro - Escherichia coli | NF001 | Absent | Absent | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| Micro - Pseudomonas aeruginosa | NF001 | Absent | Absent | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| Micro - Total Aerobic Count | NF001 | Report Results | ND | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| Test Date(s) | | | Jan 29, 2007 | Feb 28, 2007 | Apr 28, 2007 | Jul 28, 2007 | Jan 29, 2008 |

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

Stability Condition / Orientation: 40°C ± 2°C/75% RH ± 5% RH

| Specifications | | | Stability Intervals | | | | |
|--|----------------------------|---|---------------------|--------------|-------------------------|-------------------------|----------------------------|
| Test | Method | Acceptance Criteria | Initial | 1 month | 3 month | 6 month | 12 month |
| Appearance Packaging | TM001 | Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact | Conforms | Conforms | Conforms | Conforms | Conforms |
| Appearance Reconstituted - Appearance Powder | TM001 | Clear colorless solution free of visible particulate matter | Conforms | Conforms | Conforms | Conforms | Does not conform (OOS) [1] |
| Assay - Prolastin | TM002 | 90.0 to 110.0 % l.c. | 100.0 | 99.0 | 98.4 | 97.1 | 89.6 (OOS) [2] |
| Moisture | TM003 | NMT 2.0 % | 0.9 | 1.2 | 1.4 | 1.8 | 1.9 |
| pH | TM004 | 6.6 to 7.4 | 7.0 | 6.8 | 7.3 | 7.3 | 7.3 |
| Particulate Testing - 10 µm | USP 788 | NMT 6000 Counts per container | 259 | 378 | 348 | 456 | 497 |
| Particulate Testing - 25 µm | USP 788 | NMT 600 Counts per container | 23 | 129 | 45 | 57 | 145 |
| Micro - Escherichia coli | NF001 | Absent | Absent | Scheduled | Not Tested per Protocol | Not Tested per Protocol | Pending Approval |
| Micro - Pseudomonas aeruginosa | NF001 | Absent | Absent | Scheduled | Not Tested per Protocol | Not Tested per Protocol | Pending Approval |
| Micro - Total Aerobic Count | NF001 | Report Results | ND | Scheduled | Not Tested per Protocol | Not Tested per Protocol | Pending Approval |
| Test Date(s) | | | Jan 29, 2007 | Feb 28, 2007 | Apr 28, 2007 | Jul 28, 2007 | Jan 29, 2008 |
| Comments | | | | | | | |
| 1 | Refer to LIR number 398.01 | | | | | | |
| 2 | Refer to LIR number 387.00 | | | | | | |

29833 Stability Protocol Stability Summary for Generic Pharmaceuticals, Inc.

Stability Condition / Orientation: 5°C ± 3°C

| Specifications | | | Stability Intervals | | | |
|--|---------|---|---------------------|-------------------------|-------------------------|-------------------------|
| Test | Method | Acceptance Criteria | Initial | 1 month | 3 month | 6 month |
| Appearance Packaging | TM001 | Clear vial with grey rubber stopper and crimp seal with a plastic flip top intact | Conforms | Conforms | Conforms | Conforms |
| Appearance Reconstituted - Appearance Powder | TM001 | Clear colorless solution free of visible particulate matter | Conforms | Conforms | Conforms | Conforms |
| Assay - Prolastin | TM002 | 90.0 to 110.0 % I.c. | 100.0 | 100.1 | 99.9 | 99.7 |
| Moisture | TM003 | NMT 2.0 % | 0.9 | 0.9 | 1.0 | 1.0 |
| pH | TM004 | 6.6 to 7.4 | 7.0 | 7.0 | 7.0 | 7.1 |
| Particulate Testing - 10 µm | USP 788 | NMT 6000 Counts per container | 259 | 123 | 231 | 103 |
| Particulate Testing - 25 µm | USP 788 | NMT 600 Counts per container | 23 | 21 | 43 | 12 |
| Micro - Escherichia coli | NF001 | Absent | Absent | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| Micro - Pseudomonas aeruginosa | NF001 | Absent | Absent | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| Micro - Total Aerobic Count | NF001 | Report Results | ND | Not Tested per Protocol | Not Tested per Protocol | Not Tested per Protocol |
| Test Date(s) | | | Jan 29, 2007 | Feb 28, 2007 | Apr 28, 2007 | Jul 28, 2007 |

Signatures:

Reviewed By _____

Approved By _____