Catalent® Ontario Limited

DEVELOPMENT STABILITY SUMMARY REPORT

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| --- | --- | --- | --- |
| Product Description: |  | Stability Program #: | RDSP-0323 |
| Product Code / Master #: |  | Lot #: |  |
| Theoretical Batch Size: | 625,000 Capsules | Storage Conditions: | 25°C (+/- 2°)/60%RH (+/- 5%) |
| Packaging Description: |  | | |
| Active Claims: |  | | |
| Packaging Date: |  | Manufacturing Date: |  |
| Program Initiation Date: |  | Stability Chamber ID: | #2 Strathroy |

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| ACF-1541 |  |  |  |  |  |  | Specification Revision Number | 06 |
| Revision 3 |  |  |  |  |  |  |  |  |
| Sept 8 2017 | |  |  |  |  |  | Printed: | November 17, 2020 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical Property/Specification** |  | **Testing Intervals (months) and Results** | | | | | | | |
| **Method Number** | **0** | **3** | **6** | **9** | **12** | **18** | **24** | **36** |
| Description: An oval, transparent, blue, gelatin capsule. With a “XXX” logo etched across.1 | Visual | 27 |  |  |  |  |  |  |  |
| Condition of Package – Seal: The seal is intact | 3.0.6.26 |  | 28 |  |  |  |  |  |  |
| Condition of Package – Discolouration: The package is not discoloured | 3.0.6.26 |  |  | 29 |  |  |  |  |  |
| Condition of Capsules – Precipitate: No fill precipitate observed | 3.0.6.26 |  |  |  | 30 |  |  |  |  |
| Condition of Capsules – Leakers: # of leakers | 3.0.6.26 |  |  |  |  | 31 |  |  |  |
| Condition of Capsules – Clumping: Record clumping (none/minimal/moderate/extreme) | 3.0.6.26 |  |  |  |  |  | 32 |  |  |
| Condition of Capsules – Surface Defects: # of surface defects | 3.0.6.26 |  |  |  |  |  |  | 33 |  |
| Assay – Loratadine:  90.0-110.0% LC | 1.1.6.221 |  |  |  |  |  |  |  | 34 |
| Dissolution: Meets USP dissolution criteria, where Q=80% in 15 minutes  Test and Record amount dissolved in 30 minutes for each capsule | 1.1.6.421  USP <711> |  |  |  |  |  |  | 35 |  |
| Related Substances | | | | | | | | | |
| Loratadine N-Oxide: NMT 0.015% | 1.1.6.226 |  |  |  |  |  |  |  |  |
| **Analytical Property/Specification** | **Method Number** | **Testing Intervals (months) and Results** | | | | | | | |
| **0** | **3** | **6** | **9** | **12** | **18** | **24** | **36** |
| Any Unspecified Impurity:  NMT 0.2% | 1.1.6.226 |  |  |  |  |  |  |  |  |
| Total Unspecified Impurities:  NMT 0.5% | 1.1.6.226 |  |  |  |  |  |  |  |  |
| Microbiology | | | | | | | | | |
| Total (Aerobic) Microbial Count: Less than 2000 cfu/g | 1.2.6.72 |  |  |  |  |  |  |  |  |
| Salmonella Species: Absent in 10 grams | 1.2.6.62 |  |  |  |  |  |  |  |  |
| Staphylococcus Aureus: Absent in 1 gram | 1.2.6.62 |  |  |  |  |  |  |  |  |
| Escherichia Coli: Absent in 1 gram | 1.2.6.62 |  |  |  |  |  |  |  |  |
| Pseudomonas aeruginosa: Absent in 1 gram | 1.2.6.62 |  |  |  |  |  |  |  |  |
| Total (Combined) Yeast and Mold Count: Less than 200 cfu/g | 1.2.6.72 |  |  |  |  |  |  |  |  |
| Date Samples Due to be Pulled from Storage: |  |  |  |  |  |  |  |  |  |
| Actual Pull Date: |  |  |  |  |  |  |  |  |  |
| Date Testing Completed: |  |  |  |  |  |  |  |  |  |
| **Analytical Property** |  | **Testing Intervals (months) and References (Notebook/page)** | | | | | | | |
| **Method Number** | **0** | **3** | **6** | **9** | **12** | **18** | **24** | **36** |
| Description | Visual |  |  |  |  |  |  |  |  |
| Condition of Package | 3.0.6.26 |  |  |  |  |  |  |  |  |
| Condition of Capsules | 3.0.6.26 |  |  |  |  |  |  |  |  |
| Assay | 1.1.6.221 |  |  |  |  |  |  |  |  |
| Dissolution | 1.1.6.421  USP <711> |  |  |  |  |  |  |  |  |
| Related Substances | 1.1.6.226 |  |  |  |  |  |  |  |  |
| Total (Aerobic) Microbial Count | 1.2.6.72 |  |  |  |  |  |  |  |  |
| Salmonella Species | 1.2.6.62 |  |  |  |  |  |  |  |  |
| Staphylococcus Aureus | 1.2.6.62 |  |  |  |  |  |  |  |  |
| Escherichia Coli | 1.2.6.62 |  |  |  |  |  |  |  |  |
| Pseudomonas aeruginosa | 1.2.6.62 |  |  |  |  |  |  |  |  |
| Total (Combined) Yeast and Mold Count | 1.2.6.72 |  |  |  |  |  |  |  |  |

**ASSESSMENT**

1Refer to ATS 16838 for logo change.

**TEMPLATE APPROVAL SIGNATURES**

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| Template Prepared by/Date: |  |
| Template Approved by/Date: |  |

**SIGNATURES**

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| --- | --- |
| Data Recorded by/Date: |  |
| Data Integrity Reviewed by/Date: |  |
| Report Reviewed by/Date: |  |
| Report Approved by/Date: |  |