Purpose: 36-Month Stability Study on a Phase III ABCD Clinical Active Batch

Study: Manufacturer:

Product Description:

StudyName

Anonymous Pharma

DrugProduct 10mg

Study Description:

Manufacturing Date:

Lot-12345687 Lot 10mg

(Lot C) 100ct bottle

20-Sep-2020

Batch: Container:

No-123456789

100cc bottle

Batch Description: (Lot C) 100ct bottle-ABC Container Description: 100ct ABCD 100cc Bottle

Condition: 50c

Orientation : Upright

Start Date: Initial Quantity:

30-Nov-2020

40

Status:

Current Containers:

Running 26

# Condition: 25 °C/60% RH Orientation : Upright

Start Date: Initial Quantity:

30-Nov-2020

# 57

Status:

Current Containers:

Running 40

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test** | **Parameter** | **Limit** | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Disintegration, USP  <701> | Disintegration Test | Report result | (Rep 01) | N/A | N/A | N/A | N/A |
| Maximum Disintegration Time |  | (Rep 01) | 12 minutes | 11 minutes | 13 minutes | 12 minutes |
| 000279 Total Aerobic  Microbial Count | Total Aerobic Microbial Count  (CFU/g) | NMT 1QA3 CFU/g | (Rep 01) | LT100 CFU/g | NS | NS | NS |
| 000285 Yeast and Mold  Count | Yeast and Mold Count | NMT 10A2 CFU/g | (Rep 01) | LT100 CFU/g | NS | NS | NS |
| 000287 E. Coli | Escherichia coli | Absent in 1 g | (Rep 01) | Absent in 1g | NS | NS | NS |
| 000383 Water Content | Water Content | Report result | (Rep 01) | 1.5 % | 1.5 % | 1.5 % | 1.8 % |
| 000687 Appearance  (Color, Shape, Fill, Print, Leakage, Other) | Fill | Clear solution with colorless to sligh  yellow tint | (Rep 01) | Satisfactory | Satisfactory | Satisfactory | Satisfactory |
| Leakage | No evidence of leakage | (Rep 01) | Satisfactory | Satisfactory | Satisfactory | Satisfactory |
| Print | No print | (Rep 01) | Satisfactory | Satisfactory | Satisfactory | Satisfactory |
| Shape | Oblong | (Rep 01) | Satisfactory | Satisfactory | Satisfactory | Satisfactory |
| Color | Opaque red | (Rep 01) | Satisfactory | Satisfactory | Satisfactory | Satisfactory |
| Other | Report as satisfactory if no defects  or minor acceptable defects are observed | (Rep 01) | Satisfactory | Satisfactory | Satisfactory | Satisfactory |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test** | **Parameter** | **Limit** | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method A Antioxidant Assay (dl-Alpha Tocopherol) | dl-alpha tocopherol | Report Results | (Rep 01) | 11.55 mg | 11.67 mg | 11.43 mg | 11.64 mg |
| dl-alpha tocopherol (%) | Report Results | (Rep 01) | 92% | 93% | 90 % | 92% |
| Method B Assay | Assay | 54-63 mg | (Rep 01) | 60 mg | 60 mg | 60 mg | 60 mg |
| % Label Claim | 90.0 - 105.0% of label claim | (Rep 01) | 97.1 % | 98.0 % | 97.7 % | 96.8 % |
| Method B Related Substances | IQ8000 | NMT 0.5% | (Rep 01) | ND% | LTLOQ % | 0.06 % | 0.13 % |
| No 1234567 vu1 | NMT 1.0% | (Rep 01) | 0.05 % | LTLOQ % | LTLOQ % | LTLOQ % |
| No 1234567 vu2 | NMT 1.0% | (Rep 01) | LTLOQ % | LTLOQ % | LTLOQ % | LTLOQ % |
| No 1234567 vu3 | NMT 2.5% | (Rep 01) | 0.12 % | 0.14 % | 0.18 % | 0.26 % |
| Total Degradation Products | NMT 4.0% | (Rep 01) | 0.18 % | 0.10 % | 0.26% | 0.42 % |
| Method C Dissolution at 10 minutes Tier 1 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| % RSD |  | (Rep 01) | 9.3 % | 18.1 % | 31.5 % | 42.4 % |
| Average |  | (Rep 01) | 79% | 80 % | 67 % | 70% |
| Dissolution Maximum |  | (Rep 01) | 84 % | 93% | 87 % | 98% |
| Dissolution Minimum |  | (Rep 01) | 65% | 56% | 36 % | 13 % |
| Individual Unit |  | (Rep 01) | 83% | 91 % | 36 % | 94% |
| (Rep 02) | 80 % | 78% | 87 % | 97% |
| (Rep 03) | 64% | 56% | 86 % | 65% |
| (Rep 04) | 73 % | 92% | 45 % | 82% |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test Parameter Limit** | | | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method C Dissolution at 10 minutes Tier 1 | Individual Unit |  | (Rep 05) | 86 % | 78% | 79% | 15 % |
| (Rep 06) | 79% | 92% | 78 % | 96% |
| Stage |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Tier |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Method C Dissolution at 10 minutes Tier 2 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| Individual Unit |  | (Rep 01) | N/A % | N/A% | N/A% | N/A % |
| (Rep 02) | N/A % | N/A% | N/A% | N/A % |
| (Rep 03) | N/A % | N/A% | N/A% | N/A % |
| (Rep 04) | N/A% | **N/A%** | N/A% | N/A% |
| (Rep 05) | N/A % | N/A% | N/A% | N/A % |
| (Rep 06) | N/A % | N/A% | N/A% | N/A % |
| Tier |  | (Rep 01) | 2 | 2 | 2 | 2 |
| Method C Dissolution at 15 minutes Tier 1 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| % RSD |  | (Rep 01) | 3.1 % | 1.6 % | 1.7 % | 2.7% |
| Average |  | (Rep 01) | 98% | 97% | 97 % | 96% |
| Dissolution Maximum |  | (Rep 01) | 98% | 100 % | 96 % | 97% |
| Dissolution Minimum |  | (Rep 01) | 91 % | 96% | 93 % | 92 % |
| Individual Unit |  | (Rep 01) | 92 % | 98% | 98 % | 99% |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test Parameter Limit** | | | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method C Dissolution at 15 minutes Tier 1 | Individual Unit |  | (Rep 02) | 98% | 97 % | 93 % | 96% |
| (Rep 03) | 94 % | 96% | 96 % | 99% |
| (Rep 04) | 95 % | 100 % | 94 % | 98% |
| (Rep 05) | 97% | 95% | 94 % | 94 % |
| (Rep 06) | 97% | 97% | 95 % | 94% |
| Stage |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Tier |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Method C Dissolution at 15 minutes Tier 2 | Dissolution | Report Results | (Rep 01) | **N/A** | **N/A** | N/A | **N/A** |
| Individual Unit |  | (Rep 01) | **N/A%** | **N/A%** | **N/A%** | N/A% |
| (Rep 02) | N/A % | **N/A%** | N/A% | N/A % |
| (Rep 03) | N/A % | **N/A%** | **N/A%** | N/A % |
| (Rep 04) | N/A % | **N/A%** | N/A% | N/A % |
| (Rep 05) | N/A % | **N/A%** | **N/A%** | N/A % |
| (Rep 06) | **N/A%** | **N/A%** | **N/A%** | N/A% |
| Tier |  | (Rep 01) | 2 | 2 | 2 | 2 |
| Method C Dissolution Tier 1 | Dissolution | Report Results | (Rep 01) | **N/A** | **N/A** | N/A | N/A |
| % RSD |  | (Rep 01) | 3.3 % | 1.6 % | 0.8 % | 3.2% |
| Average |  | (Rep 01) | 98% | 97% | 96 % | 98% |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test** | **Parameter** | **Limit** | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method C Dissolution Tier 1 | Dissolution Maximum |  | (Rep 01) | 100 % | 99 % | 98 % | 101 % |
| Dissolution Minimum |  | (Rep 01) | 94 % | 96% | 97 % | 93% |
| Individual Unit |  | (Rep 01) | 92 % | 97% | 95 % | 101 % |
| (Rep 02) | 100 % | 96% | 94 % | 100 % |
| (Rep 03) | 95% | 97 % | 96 % | 98% |
| (Rep 04) | 98% | 100 % | 96 % | 96% |
| (Rep 05) | 98% | 96% | 95 % | 92% |
| (Rep 06) | 97% | 96% | 94 % | 100 % |
| Stage |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Tier |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Method C Dissolution Tier 2 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| Individual Unit |  | (Rep 01) | N/A % | N/A% | N/A% | N/A % |
| (Rep 02) | N/A % | N/A% | N/A% | N/A % |
| (Rep 03) | N/A% | N/A% | N/A% | N/A% |
| (Rep 04) | N/A % | N/A% | N/A% | N/A% |
| (Rep 05) | N/A % | N/A% | N/A% | N/A % |
| (Rep 06) | N/A % | N/A% | N/A% | N/A % |
| Tier | | (Rep 01) | 2 | 2 | 2 | 2 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test** | **Parameter** | **Limit** | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method C Dissolution Tier 1 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| % RSD |  | (Rep 01) | 2.2 % | 0.8% | 0.7 % | 2.5% |
| Average |  | (Rep 01) | 96% | 99% | 96 % | 100 % |
| Dissolution Maximum |  | (Rep 01) | 100 % | 100 % | 98 % | 101 % |
| Dissolution Minimum |  | (Rep 01) | 95% | 97% | 95 % | 95% |
| Individual Unit |  | (Rep 01) | 94% | 99% | 96 % | 101 % |
| (Rep 02) | 100 % | 100 % | 96 % | 100 % |
| (Rep 03) | 95% | 98% | 95 % | 102 % |
| (Rep 04) | 97% | 100 % | 97 % | 96% |
| (Rep 05) | 97% | 99% | 97 % | 96% |
| (Rep 06) | 100 % | 96% | 96 % | 100 % |
| Stage |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Tier |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Method C Dissolution Tier 2 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| Individual Unit |  | (Rep 01) | N/A % | N/A% | N/A% | N/A% |
| (Rep 02) | N/A % | N/A% | N/A% | N/A % |
| (Rep 03) | N/A % | N/A% | N/A% | N/A % |
| (Rep 04) | N/A % | N/A% | N/A% | N/A % |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test Parameter Limit** | | | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method C Dissolution Tier 2 | Individual Unit |  | (Rep 05) | N/A % | N/A% | N/A% | N/A% |
| (Rep 06) | N/A% | N/A% | N/A% | N/A % |
| Tier |  | (Rep 01) | 2 | 2 | 2 | 2 |
| Method C Dissolution Tier 1 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| % RSD |  | (Rep 01) | 54.2 % | 200.3 % | 123.7 % | 60.6 % |
| Average |  | (Rep 01) | 1% | 11 % | 11 % | 2% |
| Dissolution Maximum |  | (Rep 01) | 2% | 64% | 32 % | 5% |
| Dissolution Minimum |  | (Rep 01) | 0% | 1.2 % | 1.3 % | 0% |
| Individual Uni! |  | (Rep 01) | 1% | 65% | 1 % | 2% |
| (Rep 02) | 1% | 4% | 2% | 4% |
| (Rep 03) | 0% | 2 % | 24 % | 2% |
| (Rep 04) | 2% | 3% | 1% | 1% |
| (Rep 05) | 1% | 1% | 2% | 0% |
| (Rep 06) | 1% | 1% | 31 % | 4% |
| Stage |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Tier |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Method C Dissolution Tier 2 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| Individual Uni! |  | (Rep 01) | N/A % | N/A% | N/A% | N/A % |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test Parameter Limit** | | | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method C Dissolution Tier 2 | Individual Unit |  | (Rep 02) | N/A % | N/A% | N/A% | N/A% |
| (Rep 03) | N/A% | N/A% | N/A% | N/A % |
| (Rep 04) | N/A % | N/A% | N/A% | N/A % |
| (Rep 05) | N/A% | **N/A%** | N/A% | N/A % |
| (Rep 06) | N/A % | N/A% | N/A% | N/A % |
| Tier |  | (Rep 01) | 2 | 2 | 2 | 2 |
| Method C Dissolution Tier 1 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| % RSD |  | (Rep 01) | 2.4 % | 0.8% | 0.4 % | 1.6 % |
| Average |  | (Rep 01) | 96% | 100 % | 96 % | 100 % |
| Dissolution Maximum |  | (Rep 01) | 100 % | 100 % | 98 % | 100 % |
| Dissolution Minimum |  | (Rep 01) | 95% | 96% | 96 % | 95% |
| Individual Uni! |  | (Rep 01) | 94% | 100 % | 97 % | 99 % |
| (Rep 02) | 100 % | 100 % | 97 % | 101 % |
| (Rep 03) | 96% | 98% | 96 % | 100 % |
| (Rep 04) | 97% | 100 % | 96 % | 100 % |
| (Rep 05) | 99% | 96% | 97 % | 95% |
| (Rep 06) | 101 % | 97% | 95 % | 100 % |
| Stage | | (Rep 01) | 1 | 1 | 1 | 1 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test Parameter** | | **Limit** | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method C Dissolution Tier 1 | Tier |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Method C Dissolution Tier 2 | Dissolution | Report Results | (Rep 01) | N/A | N/A | N/A | N/A |
| Individual Unit |  | (Rep 01) | N/A % | N/A% | N/A% | N/A % |
| (Rep 02) | N/A% | **N/A%** | N/A% | N/A % |
| (Rep 03) | N/A % | N/A% | N/A% | N/A % |
| (Rep 04) | N/A % | N/A% | N/A% | N/A % |
| (Rep 05) | N/A % | N/A% | N/A% | N/A % |
| (Rep 06) | N/A % | N/A% | N/A% | N/A % |
| Tier |  | (Rep 01) | 2 | 2 | 2 | 2 |
| Method C Dissolution Q=75% of Tier 2 | Dissolution | Q=75% of Tier 2 pepsin  lest allowed | (Rep 01) | N/A | N/A | N/A | N/A |
| Individual Unit |  | (Rep 01) | N/A % | N/A% | N/A% | N/A % |
| (Rep 02) | N/A % | N/A% | N/A% | N/A % |
| (Rep 03) | N/A % | N/A% | N/A% | N/A % |
| (Rep 04) | N/A% | N/A% | N/A% | N/A% |
| (Rep 05) | N/A % | N/A% | N/A% | N/A% |
| (Rep 06) | N/A % | N/A% | N/A% | N/A % |
| Tier | | (Rep 01) | 2 | 2 | 2 | 2 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test** | **Parameter** | **Limit** | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method C Dissolution Q=75% of Tier 1 | Dissolution | Q=75% of Tier 2 pepsin  test allowed | (Rep 01) | **N/A** | Passes | Passes | Passes |
| % RSD |  | (Rep 01) | 2.3% | 1.3 % | 0.7 % | 3.3% |
| Assessment |  | (Rep 01) | Passes | Passes | Passes | Passes |
| Average |  | (Rep 01) | 95% | 100 % | 95 % | 98% |
| Dissolution Maximum |  | (Rep 01) | 101 % | 100 % | 98 % | 102 % |
| Dissolution Minimum |  | (Rep 01) | 94 % | 95% | 96 % | 92% |
| Individual Uni! |  | (Rep 01) | 92 % | 101 % | 96 % | 101 % |
| (Rep 02) | 101 % | 100 % | 97 % | 96% |
| (Rep 03) | 95% | 99% | 95 % | 97% |
| (Rep 04) | 97% | 100 % | 97 % | 94% |
| (Rep 05) | 99% | 96% | 97 % | 94% |
| (Rep 06) | 100 % | 98% | 95 % | 104 % |
| Stage |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Tier |  | (Rep 01) | 1 | 1 | 1 | 1 |
| Method D Hardness | Hardness | Report result | (Rep 01) | 8.0 **N** | 7.5 **N** | 8.0 **N** | 9.1 **N** |
| (Rep 02) | 8.4 N | 6.4 N | 7.6 N | 8.7 N |
| (Rep 03) | 8.4 N | 7.7 N | 8.5 N | 8.0 N |
| (Rep 04) | 6.5 N | 7.4 N | 9.0 N | 8.0 N |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test** | **Parameter** | **Limit** | **Replicate** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| Method D Hardness | Hardness | Report result | (Rep 05) | 7.9 **N** | 7.3 **N** | 7.9 **N** | 7.6 **N** |
| Average |  | (Rep 01) | 7.6 N | 7.3 N | 8.1 N | 8.3 N |

## Method B Related Substances

**Individual Unspecified Degradation Product**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **RRT** | **Parameter** | **Limit** | **Time Zero** | **1 Month** | **3 Months** | **6 Months** |
| 0.16 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | \* | LTLOQ | LTLOQ | LTLOQ |
| 0.25 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | LTLOQ | LTLOQ | LTLOQ | LTLOQ |
| 0.43 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | \* | \* | LTLOQ | \* |
| 0.46 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | \* | LTLOQ | \* | \* |
| 0.54 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | LTLOQ | LTLOQ | LTLOQ | LTLOQ |
| 0.63 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | \* | \* | LTLOQ | \* |
| 0.64 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | LTLOQ | LTLOQ | LTLOQ | LTLOQ |
| 0.72 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | LTLOQ | LTLOQ | LTLOQ | LTLOQ |
| 0.74 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | LTLOQ | LTLOQ | LTLOQ | \* |
| 0.72 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | \* | \* | LTLOQ | \* |
| 0.82 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | \* | LTLOQ | LTLOQ | \* |
| 0.90 | Individual Unspecified Degradation  Product (Rep 01) | NMT0.2% | \* | LTLOQ | \* | \* |

## Method B Related Substances