

STABILITY STUDY DATA SUMMARY TABLE FOR WBP2546 DP

| | | | |
|---------------------|---------------------------|----------------------|--|
| Product Name | APG777 Drug Product | Item Code | DP03671011 |
| Lot/Batch Number | 20230402 | Formulation | 20 mM Histidine buffer, 6% (w/v) Sucrose, 10 mM L-methionine, 0.04% (w/v) PS80, pH 6.0 |
| Strength | 150.0 mg/mL, 300 mg/ 2 mL | Specification Number | WX-SPEC-004866 |
| Stability Condition | 5° C ± 3° C Upright | Stability Protocol | WX-PRT-08678 |

Condition/Level: 5° C ± 3° C, Upright

Stability Start Date: 2023-04-28

| Test Item | | Acceptance Criteria | T0 | 1 M | 3 M | 6 M | 9 M | 12 M | 18 M |
|-------------------------------|-------------------|---|-----|-----|-----|-----|-----|------|------|
| Color | Color | Not more colored than No. 2 Standard Solution (Refer to EP) | B6 | B6 | BY5 | BY5 | BY5 | <B5 | <B5 |
| Clarity | Clarity | <= 30.0NTU | 5.6 | 6.1 | 5.8 | 5.8 | 5.8 | 5.9 | 6.1 |
| Visible Particles | Visible Particles | Liquid, essentially free of visible particles | (2) | (2) | (2) | (2) | (2) | (2) | (2) |
| Subvisible Particulate Matter | ≥ 10 μm | <= 6000particle(s)/container | 7 | 3 | 4 | 4 | 6 | 12 | 5 |
| | ≥ 25 μm | <= 600particle(s)/container | 0 | 0 | 0 | 0 | 0 | 0 | 2 |

Doc. No. : S23-0226-001-20230402

Report Number: 38661

Condition/Level: 5° C ± 3° C, Upright

Stability Start Date: 2023-04-28

| | | | T0 | 1 M | 3 M | 6 M | 9 M | 12 M | 18 M |
|-------------------------------|-----------------------|-----------------------------------|-------|-------|-------|-------|-------|-------|-------|
| Subvisible Particulate Matter | ≥ 2 μm | Report result particles/container | 257 | 263 | 300 | 374 | 382 | 432 | 48 |
| | ≥ 5 μm | Report result particles/container | 57 | 36 | 38 | 64 | 42 | 68 | 12 |
| pH | pH | 5.5 - 6.5 | 6.0 | 6.1 | 6.0 | 6.0 | 6.0 | 6.0 | 6.0 |
| Protein Concentration | Protein Concentration | 135.0 - 165.0mg/mL | 149.8 | 149.2 | 149.8 | 148.1 | 151.8 | 148.8 | 149.4 |
| Purity by SEC-UP LC | Monomer% (Main Peak%) | >= 93.0% | 98.9 | 98.8 | 98.8 | 98.7 | 98.5 | 98.4 | 98.3 |
| | LMWS% | <= 5.0% | ND | ND | ND | ND | 0.1 | 0.3 | 0.1 |

Confidential

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| | | | T0 | 1 M | 3 M | 6 M | 9 M | 12 M | 18 M |
|--------------------------------|---------------------------------------|----------|------|------|------|------|------|------|------|
| Purity by SEC-UP LC | HMWS% | <= 5.0% | 1.1 | 1.2 | 1.2 | 1.3 | 1.4 | 1.3 | 1.6 |
| Purity by CE-SDS (Non-reduced) | Purity% (Main Peak %) | >= 90.0% | 97.6 | 97.4 | 97.2 | 97.4 | 97.4 | 97.4 | 97.2 |
| | Total LMWS% | <= 10.0% | 2.2 | 2.3 | 2.5 | 2.3 | 2.3 | 2.4 | 2.5 |
| Purity by CE-SDS (Reduced) | Purity% (Light Chain% + Heavy Chain%) | >= 90.0% | 97.9 | 98.4 | 97.9 | 98.0 | 98.0 | 98.1 | 98.0 |
| | Total LMWS% | <= 10.0% | 1.3 | 1.0 | 1.3 | 1.2 | 1.0 | 1.1 | 1.2 |
| Charge variants by iCIEF | Main Peak% | >= 50.0% | 75.4 | 77.0 | 73.8 | 73.8 | 73.6 | 73.9 | 73.3 |

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| | | | T0 | 1 M | 3 M | 6 M | 9 M | 12 M | 18 M |
|--------------------------|------------------------|----------------------------|-------------|------|------|-------|------|-------|-------|
| Charge variants by iCIEF | Acidic Peaks% | Report result % | 19.9 | 18.7 | 21.0 | 22.0 | 21.9 | 21.2 | 21.5 |
| | Basic Peaks% | Report result % | 4.7 | 4.2 | 5.2 | 4.2 | 4.5 | 5.0 | 5.2 |
| ELISA Binding Assay | ELISA Binding Assay | 50 - 150% relative potency | 99 | 100 | 106 | 100 | 99 | 94 | 96 |
| Polysorbate 80 Content | Polysorbate 80 Content | Report result % (w/v) | 0.047%(w/v) | NT | NT | 0.036 | NT | 0.031 | 0.031 |
| CCIT | CCIT | Pass | NT | NT | NT | NT | NT | Pass | NT |

Deviation and Laboratory Investigation

| | Investigation No | Condition | TimePoint | Level | Test Item | Description |
|---------|------------------|-----------|-----------|-------|-----------|-------------|
| Sample | NA | NA | NA | NA | NA | NA |
| Test | NA | NA | NA | NA | NA | NA |
| Remark: | NA | | | | | |

Sample Information

| Condition | TimePoint | Level | Actual Pull Date | Reviewed By | Reviewed Date | Released By | Released Date |
|-------------|-----------|---------|------------------|--------------|---------------|------------------|---------------|
| | | | | QC Manager | QA Manager | | |
| 5° C ± 3° C | T0 | Upright | 2023-04-28 | XU_LI_015897 | 2024-02-01 | GUO_YULI | 2024-02-01 |
| 5° C ± 3° C | 1 M | Upright | 2023-05-29 | XU_LI_015897 | 2024-02-01 | HAN_YUANYUAN1101 | 2024-02-01 |
| 5° C ± 3° C | 3 M | Upright | 2023-07-28 | XU_LI_015897 | 2024-02-01 | HAN_YUANYUAN1101 | 2024-02-01 |
| 5° C ± 3° C | 6 M | Upright | 2023-10-30 | XU_LI_015897 | 2024-02-01 | HAN_YUANYUAN1101 | 2024-02-01 |
| 5° C ± 3° C | 9 M | Upright | 2024-01-29 | XU_LI_015897 | 2024-03-01 | GUO_YULI | 2024-03-04 |
| 5° C ± 3° C | 12 M | Upright | 2024-04-28 | XU_LI_015897 | 2024-05-21 | GUO_YULI | 2024-05-22 |
| 5° C ± 3° C | 18 M | Upright | 2024-10-28 | XU_LI_015897 | 2024-11-15 | HAN_YUANYUAN1101 | 2024-11-15 |

Footnotes:

1 NT: Test is not required

2 Liquid, essentially free of visible particles

Report History:

| Report Number | Issued Date | Level | Condition |
|---------------|-------------|---------|-----------------------|
| 32543 | 2024-05-22 | Upright | 5° C ± 3° C |
| 30215 | 2024-03-04 | Upright | 5° C ± 3° C |
| 29586 | 2024-02-05 | Upright | 40° C±2° C/75%RH±5%RH |
| 29585 | 2024-02-05 | Upright | 25° C±2° C/60%RH±5%RH |
| 29584 | 2024-02-05 | Upright | 5° C ± 3° C |
| 27642 | 2023-12-04 | Upright | 25° C±2° C/60%RH±5%RH |
| 27641 | 2023-12-04 | Upright | 5° C ± 3° C |
| 25743 | 2023-09-22 | Upright | 40° C±2° C/75%RH±5%RH |
| 25742 | 2023-09-22 | Upright | 25° C±2° C/60%RH±5%RH |
| 25740 | 2023-09-22 | Upright | 5° C ± 3° C |
| 24842 | 2023-08-21 | Upright | 40° C±2° C/75%RH±5%RH |
| 23546 | 2023-06-28 | Upright | 5° C ± 3° C |
| 23538 | 2023-06-28 | Upright | 40° C±2° C/75%RH±5%RH |
| 23536 | 2023-06-28 | Upright | 25° C±2° C/60%RH±5%RH |