

| Field / Parameter | Salicylic Acid (API) | HPMC (Binder) | Cornstarch (Disintegrant) | MCC (Filler) | Magnesium Stearate (Lubricant) |
|---------------------|----------------------------|------------------------------|------------------------------|------------------------------|--------------------------------|
| QC Reference ID | QC-RM-25-001 | QC-RM-25-002 | QC-RM-25-003 | QC-RM-25-004 | QC-RM-25-005 |
| Date of Sampling | 3-Feb-25 | 6-Feb-25 | 8-Feb-25 | 10-Feb-25 | 12-Feb-25 |
| Sampled By | Ms. A. Verma | Ms. R. Banerjee | Ramesh Pawar | Ms. R. Banerjee | Ms. R. Banerjee |
| Batch Number | SA20250127 | HPMC20241218 | CS20250304 | MC20250112 | MG20211224 |
| Material Code | RM-SA-001 | RM-HPMC-004 | RM-CS-005 | RM-MC-002 | RM-MG-003 |
| Supplier Name | Sigma-Aldrich | Sigma-Aldrich | Sigma-Aldrich | DC Fine Chemicals | Thermo-Fisher Scientific |
| Purchase Order No. | PO-SA-25-012 | PO-HPMC-25-021 | PO-CS-25-035 | PO-0891-FIL | PO-MG-25-048 |
| Date of Receipt | 2-Feb-25 | 4-Feb-25 | 7-Feb-25 | 9-Feb-25 | 11-Feb-25 |
| Sampling Location | SB-01 | SB-01 | SB-01 | SB-01 | SB-01 |
| Sampling Method | Random from each container | Random from each container | Random from each container | Random from each container | Random from each container |
| Sampling Tool | Sterile SS Scoop & Vial | Sterile SS Scoop & HDPE Vial | Sterile SS Scoop & HDPE Vial | Sterile SS Scoop & HDPE Vial | Sterile SS Scoop & HDPE Vial |
| Quarantine Status | Quarantined | Quarantined | Quarantined | Quarantined | Quarantined |
| Appearance | White crystalline powder | White to egg-white powder | White, free-flowing powder | White, odorless powder | Fine, white, odorless powder |
| Odor | Characteristic | Odorless | Odorless | Odorless | Odorless |
| Foreign Matter | None observed | None observed | None observed | None observed | None observed |
| Packaging Integrity | Intact, sealed | Intact, sealed | Intact, sealed | Intact, sealed | Intact, sealed |
| Container Condition | Good, no dents | Good, no dents | Good, no dents | Good, no dents | Good, no dents |
| Label Verification | Verified vs. PO & COA | Verified vs. PO & COA | Verified vs. PO & COA | Verified vs. PO & COA | Verified vs. PO & COA |
| Identification | Conforms (IR Spec) | Conforms (FTIR) | Conforms (FTIR) | Conforms (IR Spec) | Conforms (IR Spec) |
| Assay / Active % | 99.90% | N/A (Viscosity test) | N/A | 98.90% | 4.4% (Mg Content) |
| pH | N/A | 6.1 | 5.8 | 6.4 | N/A |
| LOD / Water Content | 0.20% | 2.80% | 10.80% | 3.80% | 2.90% |
| Melting Point | 159.5°C | N/A | N/A | N/A | 134.5°C – 137.2°C |
| Residue on Ignition | < 0.05% | 0.30% | 0.30% | 0.04% | N/A |

| | | | | | |
|-------------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| Solubility | Complies | Complies (Swells) | Complies (Insoluble) | Complies (Insoluble) | Complies (Insoluble) |
| Density | N/A | N/A | 0.62 g/mL | 0.33 g/mL | 0.21 g/mL |
| Particle Size | N/A | N/A | N/A | 91% passes #60 mesh | 96% passes #60 mesh |
| Heavy Metals | < 10 ppm |
| Microbial Load | Within Limits |
| Sterility / Endotoxin | Not Applicable |
| Specification (Assay) | 98.5% - 101.0% | 100-150 mPa·s (Visc) | N/A | 97.0% - 102.0% | 4.0% - 5.0% (Mg) |
| Observed Result | 99.90% | 135 mPa·s | N/A | 98.90% | 4.40% |
| Pass / Fail | Pass | Pass | Pass | Pass | Pass |
| Booth Cleanliness Ref. | CLN/SB01/25/005 | CLN/SB01/25/011 | CLN/SB01/25/015 | CLN/SB01/25/019 | CLN/SB01/25/023 |
| Temp / RH | 22°C / 48% RH | 21°C / 50% RH | 22°C / 51% RH | 21°C / 49% RH | 21°C / 52% RH |
| Equipment Calibration | Calibrated | Calibrated | Calibrated | Calibrated | Calibrated |
| Gowning Compliance | Compliant | Compliant | Compliant | Compliant | Compliant |
| Deviations / OOS | None | None | None | None | None |
| QC Analyst | A. Verma | P. Sharma | A. Bhardwaj | P. Sharma | A. Verma |
| Report Submission Date | 3-Feb-25 | 6-Feb-25 | 8-Feb-25 | 10-Feb-25 | 12-Feb-25 |
| QA Reviewer | Dr. A. Mehra | Dr. M. Santosh | Mr. R. Ahuja | Dr. M. Santosh | Dr. A. Mehra |
| Disposition Decision | Approved | Approved | Approved | Approved | Approved |
| Next Action | Release for Production |