

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

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