**Waylink Life Science Private Limited**

**Registered Office:** Jalan Complex Gate No1 Lane 5 Howrah 711411, West Bengal, India

# Certificate of Analysis (COA)

| | |
|---|---|
| **Customer Name:** | **Batch No.**: WLSPL – MS – 09A122025 |
| **Product Name**: Magnesium Stearate | **Grade:** IP/ USP/ BP/ EP/ JP |
| **Date of Mfg.**: December 2025 | **Date of Expiry:** November 2030 (5 years) |

| Test Parameter | Specifications | Test Value/ Reference |
|---|---|---|
| **Description** | Magnesium Stearate is a compound of magnesium with a mixture of solid organic acids, and consists variable proportions of magnesium stearate $(C_{17}H_{35}CO_2)_2Mg$, magnesium palmitate $(C_{15}H_{31}CO_2)_2Mg$ and magnesium oleate $(C_{17}H_{33}CO_2)_2Mg$ obtained from sources of vegetable or animal origin. It contains NLT 3.8% (IP2022)/ 4.0% (USP/EP/JP) and NMT 5.0% of magnesium (Mg), calculated on the dried basis. | Complies |
| **Colour & Appearance** | White or almost white, very fine, light powder, greasy to the touch; unctuous and free from grittiness. It is smooth to the touch and sticky to the skin. It has no odor or a faint, characteristic, unctuous. It is practically insoluble in water and in ethanol (99.5). | Complies |
| **Appearance of Solution (IP)** | Solution A is not more intensely colored than the reference solution YS6 (2.4.1) | Complies |
| **Appearance of Solution of the fatty acids (IP)** | Solution is clear is not more intensely colored than reference solution YS5 | Complies |
| **Solubility** | Practically insoluble in water, in anhydrous ethanol, in alcohol and in ether. | Complies |
| **Identification Test A (IP/BP/EP)** | Freezing Point 53°C Min | Complies: 57°C |
| **Identification Test A (USP)** | Solution responds to the test for Magnesium | Complies |
| **Identification (JP)** | White precipitate with ammonia, soluble in ammonium chloride, followed by formation of white crystalline precipitate with disodium hydrogen phosphate. | Complies |
| **Identification Test B (IP/BP/EP)** | Acid value is between 195 - 210 | Complies: 203 |
| **Identification Test B (USP)** | The retention times of the peaks corresponding to stearic acid and palmitic acid of the Sample solution correspond to those of the System suitability solution, as obtained in the test for Relative Content of Stearic Acid and Palmitic Acid. | Complies |
| **Identification Test C (BP/EP)** | Retention time of the principal peaks in the chromatogram obtained with the test solution are approximately the same as those of the principal peaks in the chromatogram obtained with the reference solution | Complies |
| **Identification Test C (IP)** | The test for fatty acid composition, the principal peaks in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution. | Complies |
| **Identification Test D (IP/BP/EP)** | 1ml solution A gives the reaction of Magnesium. A white crystalline precipitate is formed | Complies |

| Analyzed by | Checked by | Approved by |
|---|---|---|
| 70067079 / 18.12.2025 14:15:49 | 70067079 / 18.12.2025 14:15:49 | 724633 / 18.12.2025 14:35:03 |
| Ms. Pragati Pandey (Executive QC) | Mr. Prince Srivastava (Manager QC) | Mr. Ujjval Tiwari (Lab Head) |

This is a computer-generated document. No signature is required.

| | | |
|---|---|---|
| **Acidity/Alkalinity (IP/USP/BP/EP/JP)** | NMT 0.05 mL of 0.1 M hydrochloric acid or 0.1 M sodium hydroxide is required to change the colour of the indicator. | Complies |
| **Cadmium (USP/BP/EP)** | NMT 3.0 ppm | Complies: 0.19 |
| **Chloride (IP)** | NMT 250ppm | Complies |
| **Chloride (USP/BP/EP/JP)** | NMT 0.1% | Complies |
| **Free Stearic Acid (IP)** | NMT 3% | Complies: 0.78 |
| **Heavy Metals (IP)** | NMT 20ppm | Complies |
| **Lead (USP)** | Color of sample solution does not exceed that of the control (0.001%) | Complies: 2.39 |
| **Lead (BP/EP)** | NMT 10ppm | Complies: 2.39ppm |
| **Nickel (BP/EP)** | NMT 5.0 ppm | Complies: 0.31ppm |
| **Sulphate (IP)** | NMT 0.6% | Complies |
| **Sulphate (USP/BP/EP/JP)** | NMT 1.0% | Complies |
| **Zinc Stearate (IP)** | No violet precipitate is formed | Complies |
| **Loss on Drying (IP/USP/BP/EP/JP)** | NMT 6.0% - determined on 1g (IP/USP/BP/EP)/ 2g (JP) by drying in an oven at 105°C | Complies: 3.21% |
| **Fatty Acid (IP/USP/BP/EP)**<br>▪ **Stearic Acid**<br>▪ **Palmitic Acid + Stearic Acid** | <br>NLT 40.0%<br><br>NLT 90.0% | <br>Complies<br><br>Complies |
| **Assay (IP)** | 3.8% to 5.0% on dried basis | Complies: 4.42% |
| **Assay (USP/BP/EP)** | 4.0% to 5.0% on dried basis | Complies: 4.42 % |
| **Microbial Tests (BP/EP)** | TAMC: NMT $10^3$ cfu/g<br>TYMC: NMT $10^2$ cfu/g, Salmonella & Escherichia Coli-Absent | Complies |
| **Microbial Tests (USP/JP)** | TAMC: NMT $10^3$ cfu/g<br>TYMC: NMT $5x10^2$ cfu/g, Salmonella & Escherichia Coli-Absent | Complies |
| **Particle Size Distribution (BP/EP)** | 2.9.31 | Complies |
| **Specific Surface area (BP/EP)** | 3.0 $m^2$/gm - 14.0 $m^2$/gm | Complies: 10.49 $m^2$/gm |
| **Thermogravimetry (BP/EP)** | 2.2.34 | Complies |
| **Additional Tests** | | |
| **Bulk Density** | NMT 0.20gm/ml | Complies: 0.20gm/ml |
| **Particle Size** | Minimum 99% passing through 325mesh | 100% passes |
| **Conclusion** | The product complies with **IP2022/ USPNF 2025/ BP2025/ EP11.0/ JP 18 Pharmacopeia** | |

**Storage Conditions:** Keep in a well closed container stored under cold to warm conditions, 2 to 40°C, (36 to 104F). Protect against physical damage. Avoid dust formation and control ignition sources.

Note: If not stored as per recommended storage conditions, it may result in loss of Assay and or change in other Physico-chemical properties

| Analyzed by | Checked by | Approved by |
|---|---|---|
| 70067079 / 18.12.2025 14:15:49 | 70067079 / 18.12.2025 14:15:49 | 724633 / 18.12.2025 14:35:03 |
| Ms. Pragati Pandey (Executive QC) | Mr. Prince Srivastava (Manager QC) | Mr. Ujjval Tiwari (Lab Head) |

This is a computer-generated document. No signature is required.

Waylink Life Science Private Limited

**Registered Office:** Jalan Complex Gate No1 Lane 5 Howrah 711411, West Bengal, India

# Certificate of Analysis (COA)

| | |
|---|---|
| **Customer Name:** | **Batch No.**: WLSPL – MS – 16B122025 |
| **Product Name**: Magnesium Stearate | **Grade:** IP/ USP/ BP/ EP/ JP |
| **Date of Mfg.**: December 2025 | **Date of Expiry:** November 2030 (5 years) |

| Test Parameter | Specifications | Test Value/ Reference |
|---|---|---|
| **Description** | Magnesium Stearate is a compound of magnesium with a mixture of solid organic acids, and consists variable proportions of magnesium stearate $(C_{17}H_{35}CO_2)_2Mg$, magnesium palmitate $(C_{15}H_{31}CO_2)_2Mg$ and magnesium oleate $(C_{17}H_{33}CO_2)_2Mg$ obtained from sources of vegetable or animal origin. It contains NLT 3.8% (IP2022)/ 4.0% (USP/EP/JP) and NMT 5.0% of magnesium (Mg), calculated on the dried basis. | Complies |
| **Colour & Appearance** | White or almost white, very fine, light powder, greasy to the touch; unctuous and free from grittiness. It is smooth to the touch and sticky to the skin. It has no odor or a faint, characteristic, unctuous. It is practically insoluble in water and in ethanol (99.5). | Complies |
| **Appearance of Solution (IP)** | Solution A is not more intensely colored than the reference solution YS6 (2.4.1) | Complies |
| **Appearance of Solution of the fatty acids (IP)** | Solution is clear is not more intensely colored than reference solution YS5 | Complies |
| **Solubility** | Practically insoluble in water, in anhydrous ethanol, in alcohol and in ether. | Complies |
| **Identification Test A (IP/BP/EP)** | Freezing Point 53°C Min | Complies: 57°C |
| **Identification Test A (USP)** | Solution responds to the test for Magnesium | Complies |
| **Identification (JP)** | White precipitate with ammonia, soluble in ammonium chloride, followed by formation of white crystalline precipitate with disodium hydrogen phosphate. | Complies |
| **Identification Test B (IP/BP/EP)** | Acid value is between 195 - 210 | Complies: 203 |
| **Identification Test B (USP)** | The retention times of the peaks corresponding to stearic acid and palmitic acid of the Sample solution correspond to those of the System suitability solution, as obtained in the test for Relative Content of Stearic Acid and Palmitic Acid. | Complies |
| **Identification Test C (BP/EP)** | Retention time of the principal peaks in the chromatogram obtained with the test solution are approximately the same as those of the principal peaks in the chromatogram obtained with the reference solution | Complies |
| **Identification Test C (IP)** | The test for fatty acid composition, the principal peaks in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution. | Complies |
| **Identification Test D (IP/BP/EP)** | 1ml solution A gives the reaction of Magnesium. A white crystalline precipitate is formed | Complies |

| Analyzed by | Checked by | Approved by |
|---|---|---|
| 70067079 / 18.12.2025 14:15:49 | 70067079 / 18.12.2025 14:15:49 | 724633 / 18.12.2025 14:35:03 |
| Ms. Pragati Pandey (Executive QC) | Mr. Prince Srivastava (Manager QC) | Mr. Ujjval Tiwari (Lab Head) |

This is a computer-generated document. No signature is required.

| | | |
|---|---|---|
| **Acidity/Alkalinity (IP/USP/BP/EP/JP)** | NMT 0.05 mL of 0.1 M hydrochloric acid or 0.1 M sodium hydroxide is required to change the colour of the indicator. | Complies: 0.13 |
| **Cadmium (USP/BP/EP)** | NMT 3.0 ppm | Complies: 0.19 |
| **Chloride (IP)** | NMT 250ppm | Complies |
| **Chloride (USP/BP/EP/JP)** | NMT 0.1% | Complies |
| **Free Stearic Acid (IP)** | NMT 3% | Complies |
| **Heavy Metals (IP)** | NMT 20ppm | Complies |
| **Lead (USP)** | Color of sample solution does not exceed that of the control (0.001%) | Complies |
| **Lead (BP/EP)** | NMT 10ppm | Complies: 2.42 |
| **Lead (BP)** | Max 10.0ppm | Complies |
| **Nickel (BP/EP)** | NMT 5.0 ppm | Complies: 0.28ppm |
| **Sulphate (IP)** | NMT 0.6% | Complies |
| **Sulphate (USP/BP/EP/JP)** | NMT 1.0% | Complies |
| **Zinc Stearate (IP)** | No violet precipitate is formed | Complies |
| **Loss on Drying (IP/USP/BP/EP/JP)** | NMT 6.0% - determined on 1g (IP/USP/BP/EP)/ 2g (JP) by drying in an oven at 105°C | Complies: 2.41% |
| **Fatty Acid (IP/USP/BP/EP)**<br>▪ **Stearic Acid**<br>▪ **Palmitic Acid + Stearic Acid** | <br>NLT 40.0%<br><br>NLT 90.0% | <br>Complies<br><br>Complies |
| **Assay (IP)** | 3.8% to 5.0% on dried basis | Complies: 4.41% |
| **Assay (USP/BP/EP)** | 4.0% to 5.0% on dried basis | Complies: 4.41% |
| **Microbial Tests (BP/EP)** | TAMC: NMT $10^3$ cfu/g<br>TYMC: NMT $10^2$ cfu/g, Salmonella & Escherichia Coli-Absent | Complies |
| **Microbial Tests (USP/JP)** | TAMC: NMT $10^3$ cfu/g<br>TYMC: NMT $5x10^2$ cfu/g, Salmonella & Escherichia Coli-Absent | Complies |
| **Particle Size Distribution (BP/EP)** | 2.9.31 | Complies |
| **Specific Surface area (BP/EP)** | 3.0 $m^2$/gm - 14.0 $m^2$/gm | Complies: 10.52 $m^2$/gm |
| **Thermogravimetry (BP/EP)** | 2.2.34 | Complies |
| **Additional Tests** | | |
| **Bulk Density** | NMT 0.20gm/ml | Complies: 0.18gm/ml |
| **Particle Size** | Minimum 99% passing through 325mesh | 100% passes |
| **Conclusion** | The product complies with **IP2022/ USPNF 2025/ BP2025/ EP11.0/ JP 18 Pharmacopeia** | |

**Storage Conditions:** Keep in a well closed container stored under cold to warm conditions, 2 to 40°C, (36 to 104F). Protect against physical damage. Avoid dust formation and control ignition sources.

Note: If not stored as per recommended storage conditions, it may result in loss of Assay and or change in other Physico-chemical properties

| Analyzed by | Checked by | Approved by |
|---|---|---|
| 70067079 / 18.12.2025 14:15:49 | 70067079 / 18.12.2025 14:15:49 | 724633 / 18.12.2025 14:35:03 |
| Ms. Pragati Pandey (Executive QC) | Mr. Prince Srivastava (Manager QC) | Mr. Ujjval Tiwari (Lab Head) |

This is a computer-generated document. No signature is required.

**Waylink Life Science Private Limited**

**Registered Office:** Jalan Complex Gate No1 Lane 5 Howrah 711411, West Bengal, India

## Certificate of Analysis (COA)

| | |
|---|---|
| **Customer Name:** | **Batch No.**: WLSPL – MS – 16C122025 |
| **Product Name**: Magnesium Stearate | **Grade:** IP/ USP/ BP/ EP/ JP |
| **Date of Mfg.**: December 2025 | **Date of Expiry:** November 2030 (5 years) |

| Test Parameter | Specifications | Test Value/ Reference |
|---|---|---|
| **Description** | Magnesium Stearate is a compound of magnesium with a mixture of solid organic acids, and consists variable proportions of magnesium stearate $(C_{17}H_{35}CO_2)_2Mg$, magnesium palmitate $(C_{15}H_{31}CO_2)_2Mg$ and magnesium oleate $(C_{17}H_{33}CO_2)_2Mg$ obtained from sources of vegetable or animal origin. It contains NLT 3.8% (IP2022)/ 4.0% (USP/EP/JP) and NMT 5.0% of magnesium (Mg), calculated on the dried basis. | Complies |
| **Colour & Appearance** | White or almost white, very fine, light powder, greasy to the touch; unctuous and free from grittiness. It is smooth to the touch and sticky to the skin. It has no odor or a faint, characteristic, unctuous. It is practically insoluble in water and in ethanol (99.5). | Complies |
| **Appearance of Solution (IP)** | Solution A is not more intensely colored than the reference solution YS6 (2.4.1) | Complies |
| **Appearance of Solution of the fatty acids (IP)** | Solution is clear is not more intensely colored than reference solution YS5 | Complies |
| **Solubility** | Practically insoluble in water, in anhydrous ethanol, in alcohol and in ether. | Complies |
| **Identification Test A (IP/BP/EP)** | Freezing Point 53°C Min | Complies: 59°C |
| **Identification Test A (USP)** | Solution responds to the test for Magnesium | Complies |
| **Identification (JP)** | White precipitate with ammonia, soluble in ammonium chloride, followed by formation of white crystalline precipitate with disodium hydrogen phosphate. | Complies |
| **Identification Test B (IP/BP/EP)** | Acid value is between 195 - 210 | Complies: 201 |
| **Identification Test B (USP)** | The retention times of the peaks corresponding to stearic acid and palmitic acid of the Sample solution correspond to those of the System suitability solution, as obtained in the test for Relative Content of Stearic Acid and Palmitic Acid. | Complies |
| **Identification Test C (BP/EP)** | Retention time of the principal peaks in the chromatogram obtained with the test solution are approximately the same as those of the principal peaks in the chromatogram obtained with the reference solution | Complies |
| **Identification Test C (IP)** | The test for fatty acid composition, the principal peaks in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution. | Complies |
| **Identification Test D (IP/BP/EP)** | 1ml solution A gives the reaction of Magnesium. A white crystalline precipitate is formed | Complies |

| Analyzed by | Checked by | Approved by |
|---|---|---|
| 70067079 / 18.12.2025 14:15:49 | 70067079 / 18.12.2025 14:15:49 | 724633 / 18.12.2025 14:35:03 |
| Ms. Pragati Pandey (Executive QC) | Mr. Prince Srivastava (Manager QC) | Mr. Ujjval Tiwari (Lab Head) |

This is a computer-generated document. No signature is required.

| | | |
|---|---|---|
| **Acidity/Alkalinity (IP/USP/BP/EP/JP)** | NMT 0.05 mL of 0.1 M hydrochloric acid or 0.1 M sodium hydroxide is required to change the colour of the indicator. | Complies |
| **Cadmium (USP/BP/EP)** | NMT 3.0 ppm | Complies: 0.21 |
| **Chloride (IP)** | NMT 250ppm | Complies |
| **Chloride (USP/BP/EP/JP)** | NMT 0.1% | Complies |
| **Free Stearic Acid (IP)** | NMT 3% | Complies: 0.84 |
| **Heavy Metals (IP)** | NMT 20ppm | Complies |
| **Lead (USP)** | Color of sample solution does not exceed that of the control (0.001%) | Complies |
| **Lead (BP/EP)** | NMT 10ppm | Complies: 2.38ppm |
| **Nickel (BP/EP)** | NMT 5.0 ppm | Complies: 0.32ppm |
| **Sulphate (IP)** | NMT 0.6% | Complies |
| **Sulphate (USP/BP/EP/JP)** | NMT 1.0% | Complies |
| **Zinc Stearate (IP)** | No violet precipitate is formed | Complies |
| **Loss on Drying (IP/USP/BP/EP/JP)** | NMT 6.0% - determined on 1g (IP/USP/BP/EP)/ 2g (JP) by drying in an oven at 105°C | Complies: 2.34% |
| **Fatty Acid (IP/USP/BP/EP)**<br>▪ **Stearic Acid**<br>▪ **Palmitic Acid + Stearic Acid** | <br>NLT 40.0%<br><br>NLT 90.0% | <br>Complies<br><br>Complies |
| **Assay (IP)** | 3.8% to 5.0% on dried basis | Complies: 4.43% |
| **Assay (USP/BP/EP)** | 4.0% to 5.0% on dried basis | Complies: 4.43 % |
| **Microbial Tests (BP/EP)** | TAMC: NMT $10^3$ cfu/g<br>TYMC: NMT $10^2$ cfu/g, Salmonella & Escherichia Coli-Absent | Complies |
| **Microbial Tests (USP/JP)** | TAMC: NMT $10^3$ cfu/g<br>TYMC: NMT $5x10^2$ cfu/g, Salmonella & Escherichia Coli-Absent | Complies |
| **Particle Size Distribution (BP/EP)** | 2.9.31 | Complies |
| **Specific Surface area (BP/EP)** | 3.0 $m^2$/gm - 14.0 $m^2$/gm | Complies: 10.59 $m^2$/gm |
| **Thermogravimetry (BP/EP)** | 2.2.34 | Complies |
| **Additional Tests** | | |
| **Bulk Density** | NMT 0.20gm/ml | Complies: 0.19gm/ml |
| **Particle Size** | Minimum 99% passing through 325mesh | 100% passes |
| **Conclusion** | The product complies with **IP2022/ USPNF 2025/ BP2025/ EP11.0/ JP 18 Pharmacopeia** | |

**Storage Conditions:** Keep in a well closed container stored under cold to warm conditions, 2 to 40°C, (36 to 104F). Protect against physical damage. Avoid dust formation and control ignition sources.

Note: If not stored as per recommended storage conditions, it may result in loss of Assay and or change in other Physico-chemical properties

| Analyzed by | Checked by | Approved by |
|---|---|---|
| 70067079 / 18.12.2025 14:15:49 | 70067079 / 18.12.2025 14:15:49 | 724633 / 18.12.2025 14:35:03 |
| Ms. Pragati Pandey (Executive QC) | Mr. Prince Srivastava (Manager QC) | Mr. Ujjval Tiwari (Lab Head) |

This is a computer-generated document. No signature is required.