

Specification

AMT106323 Sodium hydrogen carbonate suitable for use as excipient

| <u>Test</u> | <u>Specification</u> |
|------------------------------|-----------------------|
| Assay (on dried substance) | 99.5-100.5 % |
| Identity | Meet the requirements |
| Fe(Iron) | ≤0.002 % |
| Heavy metals(as Pb) | ≤0.0005 % |
| Residual solvents | Meet the requirements |
| Chloride (Cl) | ≤ 0.015 % |
| Sulphate(SO ₄) | ≤0.01 % |
| Appearance of solution | Meet the requirements |
| Carbonate (CO ₃) | Meet the requirements |
| Loss on drying (Silicagel) | ≤ 0.25 % |
| pH-Value | |
| -(1%, water) | 8.0-8.6 |
| -(5%, water) | 7.9-8.4 |

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