



**Jinan Hongfangde Pharmatech Co., Ltd.**

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## CERTIFICATE OF ANALYSIS

|              |               |             |            |
|--------------|---------------|-------------|------------|
| Product name | Articaine HCl | CAS         | 23964-57-0 |
| Batch No.    | 20190201      | Expiry date | 2021-01-30 |
| Report Date  | 2019-02-10    | Quantity    | 1250kg     |

| Item              | Specification                                            | Result                       |
|-------------------|----------------------------------------------------------|------------------------------|
| Appearance        | White or almost white crystalline power                  | White crystalline powder     |
| Solubility        | Soluble in Water and ethanol                             | Soluble in Water and ethanol |
| Indentification   | A:Max abosorption at 272nm                               | Max abosorption at 272nm     |
|                   | B: By IR, To match with working standard                 | Conform                      |
|                   | C: By TLC,Should to match with working standard          | Conform                      |
|                   | D:Chloride reaction                                      | Conform                      |
| Clarity and color | Water solution should be clear;Should be lighter than Y6 | Conform                      |
| pH                | 4.2~5.2                                                  | 4.60                         |



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|                     |                                     |                 |
|---------------------|-------------------------------------|-----------------|
| Relative substance  | ImpurityA $\leq 0.2\%$              | No detected     |
|                     | Other impurity $\leq 0.1\%$         | 0.06%           |
|                     | Total impurity $\leq 0.5\%$         | 0.15%           |
|                     | Unknown impurity $\leq 0.05\%$      | 0.03%           |
| Heavy metal         | $\leq 5\text{ppm}$                  | $< 5\text{ppm}$ |
| Loss on drying      | $\leq 0.5\%$                        | 0.20%           |
| Residue on ignition | $\leq 0.1\%$                        | 0.08%           |
| Assay (HPLC)        | 98.5% ~ 101.0% (On anhydrous basis) | 99.85%          |
| Conclusion          | Conforms to USP39                   |                 |

Analyst :shilijuan    Checker: maohongjun    Supervisor :wangsulan