

Certificate of Analysis

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|-----------------------|--------------------------|--------------------|-------------|
| Product name | Umifenovir Hydrochloride | Mfg. Date | 2021.05.09 |
| Batch No: | KN2210509 | Test date | 2021.05.11 |
| Batch quantity | 800kg | Expiry date | 2023. 05.08 |

| Items | Specifications | Results |
|---|---|---------------------|
| Appearance | White or almost white powder | Almost white powder |
| Absorption factor | Should be 385-409 | 399 |
| Identification | | |
| 1 | Should produce orange red precipitate | Complies |
| 2 | In the chromatogram of content determination, the retention time of the main peak of the sample solution should be consistent with that of the standard solution. | Complies |
| 3 | The infrared absorption spectra should be consistent with the standard samples. | Complies |
| 4 | The identification reaction of filtrate should be chloride. | Complies |
| Tests | | |
| Clarify and color of ethanol solution | Solution clarity should be less than No.1 turbidity standard solution. | Complies |
| | The color should be lighter than No.3 yellow green or No.3 brown red standard color solution. | Complies |
| Ph | 4.0 - 6.0 | 4.3 |
| Burning residue | ≤ 0.2% | 0.1% |
| Water | 3.0% - 4.0% | 3.4% |
| Heavy metals | ≤ 10 ppm | < 10 ppm |
| Residual solvents | Ethanol ≤ 0.5% | 0.02% |
| | Acetone ≤ 0.5% | 0.01% |
| Related substances | Single impurity ≤ 0.5% | 0.2% |
| | Total impurity ≤ 1.0% | 0.6% |
| Microorganism | Total number of aerobic bacteria ≤ 1000 cfu/g | 20 cfu/g |
| | Total number of mucedines and yeasts ≤ 100 cfu/g | < 10 cfu/g |
| Assay | No less than 98.0% and no more than 102.0% on anhydrous. Calculate as $C_{22}H_{25}BrN_2O_3S \cdot HCl$ | 100.3% |
| Conclusion: Complies with the Second enlarged edition of <i>Chinese Pharmacopoeia 2010</i> | | |

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