漯河南街村药业集团制药有限公司
LUOHE NANJIECUN PHARMACEUTICAL GROUP PHARMACY CO., LTD
ADD:NO.7, RENMIN ROAD (EAST), LUOHE CITY, HENAN PROVINCE, P.R.CHINA.

# CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| PRODUCT: | RIFAPENTINE | QUANTITY: | SAMPLE |
| BATCH NO.: | 20080401 | MFG. DATE: | 04/20/2008 |
| PACKING: | 20KG/DRUM | EXP. DATE: | 04/20/2012 |
| FOUNDATION: | CP2005 | DATE OF REPORT: | 04/27/2008 |

| Sr No. | Items | Specifications | Observation |
|---|---|---|---|
| 01 | Character | Brick red or dark red, odorless, crystalline powder | Brick red crystalline powder, odorless. |
| 02 | Identification | | |
| | a) HPLC | The retention time of the principal peak of the test solution should correspond to that of the principal peak of the reference solution. | Complies |
| | b) UV spectromctry | Maximum absorption should be obtained at the wavelength of 236nm, 255nm, 334nm and 474nm | Complies |
| | c) IR spectrometry | The spectrum obtained with the substance should correspond to the standard spectrum. | Complies |
| 03 | Crystallinity | Meet the requirement | Complies |
| 04 | PH-value | 4.0-8.0 | 6.96 |
| 05 | Residual solvents | | |
| | a) Butanol | NMT 1.0% | 0.56% |
| | b) Ethanol | 1.0%~3.5% | 2.91% |
| 06 | Related substances | Meet the requirement | Complies |
| 07 | Loss on drying | 1.5%~5.0% | 1.55% |
| 08 | Residue on Ignition | NMT 0.2% | 0.08% |
| 09 | Heavy metals | NMT 20ppm | Complies |
| 10 | Particle size | The number of the particles with the size of over 50um are NMT 20 particles | Complies |
| 11 | Abnormal toxicity | Meet the requirement (12 mg/ml, 0.5ml/rat, oral administration) | Complies |
| 12 | Microbiological limit | E.Coli: absent; viable acarus: absent; bateria count: NMT 1000 CFU/g; mold: NMT100CFU/g | Complies |
| 13 | Assay (HPLC method) | NLT 93.5% | 96.80% |

This is certified that we, the undersigned, have inspected the quality of above-mentioned goods as manufacturer and found the result as following:

Conclusion is up to the Standard of CP2005

LUOHE NANJIECUN PHARMACEUTICAL GROUP PHARMACY CO.,LTD
漯河南街村药业集团制药有限公司

Approved by: 徐龙 Checked by: 张素芳 Analysed by: 李会荣

漯河南街村药业集团制药有限公司
LUOHE NANJIECUN PHARMACEUTICAL GROUP PHARMACY CO., LTD
ADD:NO.7, RENMIN ROAD (EAST), LUOHE CITY, HENAN PROVINCE, P.R.CHINA.

# CERTIFICATE OF ANALYSIS

| | | | |
|---|---|---|---|
| PRODUCT: | RIFAPENTINE | QUANTITY: | SAMPLE |
| BATCH NO.: | 20080402 | MFG. DATE: | 04/22/2008 |
| PACKING: | 20KG/DRUM | EXP. DATE: | 04/22/2012 |
| FOUNDATION: | CP2005 | DATE OF REPORT: | 04/29/2008 |

| Sr No. | Items | Specifications | Observation |
|---|---|---|---|
| 01 | Character | Brick red or dark red, odorless, crystalline powder | Brick red crystalline powder, odorless. |
| 02 | Identification | | |
| | a) HPLC | The retention time of the principal peak of the test solution should correspond to that of the principal peak of the reference solution. | Complies |
| | b) UV spectromctry | Maximum absorption should be obtained at the wavelength of 236nm, 255nm, 334nm and 474nm | Complies |
| | c) IR spectrometry | The spectrum obtained with the substance should correspond to the standard spectrum. | Complies |
| 03 | Crystallinity | Meet the requirement | Complies |
| 04 | PH-value | 4.0-8.0 | 6.93 |
| 05 | Residual solvents | | |
| | a) Butanol | NMT 1.0% | 0.57% |
| | b) Ethanol | 1.0%~3.5% | 2.86% |
| 06 | Related substances | Meet the requirement | Complies |
| 07 | Loss on drying | 1.5%~5.0% | 1.53% |
| 08 | Residue on Ignition | NMT 0.2% | 0.07% |
| 09 | Heavy metals | NMT 20ppm | Complies |
| 10 | Particle size | The number of the particles with the size of over 50um are NMT 20 particles | Complies |
| 11 | Abnormal toxicity | Meet the requirement (12 mg/ml, 0.5ml/rat, oral administration) | Complies |
| 12 | Microbiological limit | E.Coli: absent; viable acarus: absent; bateria count: NMT 1000 CFU/g; mold: NMT100CFU/g | Complies |
| 13 | Assay (HPLC method) | NLT 93.5% | 96.75% |

This is certified that we, the undersigned, have inspected the quality of above-mentioned goods as manufacturer and found the result as following:

Conclusion is up to the Standard of CP2005

LUOHE NANJIECUN PHARMACEUTICAL GROUP PHARMACY CO., LTD
漯河南街村药业集团制药有限公司

Approved by: 峰万印涨 Checked by: 张建花 Analysed by: 李令令