



湖北广济药业股份有限公司
HUBEI GUANGJI PHARMACEUTICAL CO., LTD.

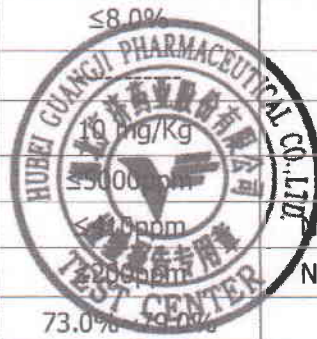
检 验 报 告 单

Certificate of Analysis

| | | | |
|------------------|-----------------------------|-------------------|-------------|
| Name of Product: | RIBOFLAVIN SODIUM PHOSPHATE | Certificate No. : | 2021024 |
| Batch Number : | 2021024 | Manu.Date : | MAY.26,2021 |
| Batch Size : | 1000kg | Date of Release: | JUN.19,2021 |
| Packing Size : | 10kg | Expiry Date : | MAY.25,2023 |

Test Reference EUROPEAN PHARMACOPEIA X (EP10) & BRITISH PHARMACOPEIA 2020 (BP2020) & UNITED STATES PHARMACOPEIA 2021 (USP2021)

| Test Items | USP2021 | | BP2020 & EP10 | |
|-------------------------|--|----------|-------------------------------|--------------|
| | Specification | Result | Specification | Result |
| 1. Appearance | Yellow to orange yellow crystalline powder | | | |
| 2. Identification | Be Positive | Positive | Be Positive | Positive |
| 3. pH | 5.0 ~ 6.5 | 6.2 | 5.0 ~ 6.5 | 6.2 |
| 4. Specific Rotation | +37.0° ~ +42.0° | +38.4° | +38.0° ~ +43.0° | +39.5° |
| 5. Limit Of Lumiflavin | ≤0.025 | 0.004 | Comply | Comply |
| 6. Related Substances | Free Riboflavin or Riboflavin | 2.5% | Free Riboflavin or Riboflavin | 2.6% |
| | di-Phosphate NMT 6.0% | 1.7% | di-Phosphate NMT 6.0% | 1.8% |
| 7. Inorganic Phosphate | ----- | ----- | ≤1.5% | Comply |
| 8. Free Phosphate | A sample solution ≤ A control solution | Comply | | |
| 9. Loss On Drying | ≤7.5% | 4.1% | ≤8.0% | 4.1% |
| 10. Residue On Ignition | ≤25.0% | 22.1% | ----- | ----- |
| 11. Heavy Metals | ----- | ----- | ----- | Comply |
| 12. Residual Solvents | Ethanol | ≤5000ppm | 200ppm | 200ppm |
| | Acetonitrile | ≤410ppm | Not detected | Not detected |
| | Pyridine | ≤200ppm | Not detected | Not detected |
| 13. Assay | 73.0% ~ 79.0% | 73.8% | 73.0% ~ 79.0% | 74.4% |



Conclusion

This Batch Complies With USP 2021, BP 2020 & EP 10

检验人: 郭文静
Analyst

审核人: 韩丽平
Audit people

批准人:
Approval

