

No.: BPAP-605-A-00/3.0

CERTIFICATE OF ANALYSIS

| | | | |
|----------------------|---------------------|--------------------|---------------|
| Product Name | Quetiapine Fumarate | CAS No. | 111974-72-2 |
| Batch No. | P020760519A | Mfg. Date | Jul. 12, 2019 |
| Quantity | 5kg | Retest Date | Jul. 11, 2021 |
| Packing | 5kg/Bag | Report Date | Jul. 17, 2019 |
| Specification | EP | | |

| ITEM | SPECIFICATION | RESULT |
|--------------------------------------|--|--------------|
| Appearance | White or almost white powder | White powder |
| Solubility | Slight soluble in water, in anhydrous ethanol and in methanol | Complies |
| Identification | The IR spectrum of sample is identical with that of reference standard | Complies |
| Loss on Drying | ≤0.5% | 0.07% |
| Sulfated ash | ≤0.1% | <0.1% |
| Heavy Metals | ≤10ppm | Complies |
| Assay (dried substance) | Fumaric acid: 12.5%~13.8% | 13.2% |
| | Quetiapine Fumarate:99.0%~101.0% | 100% |
| Related Substances (HPLC) | Impurity G ≤0.15% | Undetected |
| | Impurity N ≤0.15% | Undetected |
| | Any unspecified impurity≤0.10% | <0.05% |
| | Total impurities ≤0.5% | 0.1% |
| Conclusion | Comply with the specification. | |
| Storage | Preserve in tight containers, protected from strong light and high heat. | |

Analyst:

Reviewed by:

Approved by: