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Hegno

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CERTIFICATE OF ANALYSIS

No.: ZL-QC923-01

Product: Griseofulvin BP (Working Standard)

| Batch No.: HH141129 | | Date of Analysis: 25.11.2015 |
|--------------------------------------|--|------------------------------------|
| MFG. Date: Nov. 20,2015 | | Use before: 25.11.2016 |
| EXP. Date: Nov. 20,2020 | | Quantity: 1.0 g |
| Tests | Specifications | Results |
| Appearance | White or yellowish-white, microfine powder. | Yellowish-white, microfine powder. |
| Solubility | Practically insoluble in water, freely soluble in dimethylformamide and in tetrachloroethane, slightly soluble in anhydrous ethanol and in methanol. | Meets the requirements. |
| Identification | A: IR | Meets the requirements. |
| | B: Color Test | Meets the requirements. |
| Particle size | $\leq 5 \mu\text{m} \geq 87.0\%$ | 94.46% |
| | $\leq 10 \mu\text{m} \geq 90.0\%$ | 99.54% |
| | $\leq 30 \mu\text{m} \geq 99.0\%$ | 100.00% |
| Melting point | About 220°C | 218.5°C – 219.4°C |
| Acidity | 0.25 g consumed 0.02 M sodium hydroxide not more than 1.0 ml. | 0.6 ml |
| Appearance of solution | The solution is clear and not more intensely colored than reference solution Ys ₄ . | Clear, Ys ₄ . |
| Specific optical rotation | +354° to +364° | + 357° |
| Substance soluble in light petroleum | $\leq 0.2\%$ | 0.1% |
| Sulphated ash | $\leq 0.2\%$ | 0.1% |
| Loss on drying | $\leq 1.0\%$ | 0.11% |
| Related substances | -Cl: ≤ 0.60 | 0.46 |
| | -H: ≤ 0.15 | 0.11 |
| Abnormal toxicity | According to BP2011/EP7 | Meets the requirements. |
| Content (dried substance) | 97.0% to 102.0% | 99.11% |
| Heavy metal | $\leq 0.002\%$ | < 0.002% |

Conclusion: The above analytical results conform to BP2013

N. S. Singh
QA Manager: 25/11/15

QC Manager: 25/11/15

Analyst: 25/11/15

