GULF PHARMACEUTICAL INDUSTRIES

Ras Al Khaimah, Post Box No. 997 Tel.: +9717-2461461, Fax: +9717-2462462 United Arab Emirates

Julphar

Quality Control Department

شردة الخليج للصناعات الدوانية

راس الخيمة - ص.ب. ۱۹۹۷ تليفون : ۲۶۱۲۶۱۱ ۲۹۰۷۰ فاكس : ۲۶۱۲۶۲۲ ۹۷۱۷ ۲مارات العربية المتحدة

> WRS FI-9

WRS

<u>Certificate of Analysis</u> <u>Secondary Reference Standard</u>

Name: Fluconazole Material No: 10000333 Batch No: 0000032352/III Insp. Lot No: 10000031770

| Test | Specification | Result |
|-------------------|---|---|
| Description | White or almost white, crystalline powder, free from extraneous substances like black particles. | Conform |
| Identification | To pass tests under analytical method. | Conform |
| Loss on drying | NMT 0.50% | 0.19% |
| Related compounds | Fluconazole related compound A: NMT 0.20% | 0.005% |
| | Fluconazole related compound B: NMT 0.10% | 0.00% |
| | Fluconazole related compound C: NMT 0.20% | 0.00% |
| | Any impurity with RRT about 0.60: NMT 1.0% | 0.27% |
| | Any other single impurity: NMT 0.10% | 0.00% |
| | Total unknown impurities: NMT 0.30% | 0.00% |
| | Total impurities: NMT 1.50% | 0.28% |
| Assay | NLT 98.0% and NMT 102.0% of C ₁₃ H ₁₂ F ₂ N ₆ O, calculated on the dried basis. | 99.58% (as is basis) 99.77% (on dried basis) |

Standardization date: 07/12/2015

Standardized by: Gohar

Exp. date: 12/2016

Weight per vial: 500mg

Checked by: Pensee Mohamed, B. S. Pharm Quality Control Deputy Manager

Head of Quality Control Department Sheikha Khamis

ARTME