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QUALITY ASSURANCE DEPARTMENT WORKING STANDARD- CERTIFICATE OF ANALYSIS



| Product Name | GEFITINIB - WO | ORKING STANDARD | |
|------------------|----------------------|---------------------------------|--------------------------|
| Batch No. | BD/GF/WS/16/01 | A.R.No. | BD/WS/GFZN140008/01 |
| Date of Analysis | 20/01/2016 | Date of Issue | 22/01/2016 |
| Mfg. Date | Jan-2016 | Retest Date | 21/01/2017 |
| Exp. Date | Dec-2019 | Primary Working Std. No. | GF/WS/15/01 |
| Storage | Store protect from 1 | ight and moisture, at a tempera | ture not exceeding 25°C. |

| S.No. | TEST | STANDARD | RESULT |
|-------|------------------------|---|-------------------------------|
| 1. | Description | White to off white crystalline powder | Off white crystalline powder. |
| 2. • | Identification | The IR Spectrum of sample should concordant with similar preparation of that of Gefitinib working standard. | Complies |
| 3. | Loss on drying | NMT 1.0% w/w | 0.1% |
| 4. | Assay (On dried basis) | NLT 98.0% and NMT 102.0% | 99.95% |
| 5. | Potency | For information | 99.85 % |

Remarks: The sample complies /does not comply as per In-House Specification.



PREPARED BY

Checked By:

ApprovedBy

QA Officer Nilam Parikh Organo 15016

QC Manager 22

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