

C₁-3 3C₁-3

QUALITY ASSURANCE DEPARTMENT
WORKING STANDARD- CERTIFICATE OF ANALYSIS



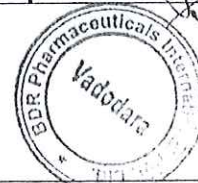
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|-------------------------|---|---------------------------|-----------------------|
| Product Name | CAPECITABINE USP- WORKING STANDARD | | |
| Batch No. | BD/CP/WS/16/01 | A.R.No. | BD/CP/WS/COA/16/01/01 |
| Date of Analysis | 15/01/2016 | Date of Issue | 16/01/2016 |
| Mfg. Date | Jan-2016 | Retest Date | 15/01/2017 |
| Exp. Date | Dec-2018 | Reference Std. No. | R014M0 |
| Storage | Preserve in well-closed containers, and store at controlled room temperature. | | |

| S.No. | TEST | STANDARD | RESULT |
|-------|---|---|---|
| 1. | Description | White to off-white crystalline powder. | White crystalline powder. |
| 2. | Identification A) By IR: B) By HPLC: | The IR spectrum of sample is in accordance with that of reference standard The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. | The IR spectrum of sample is in accordance with that of reference standard The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. |
| 3. | Water Determination | NMT 0.3 % | 0.1 % |
| 4. | Assay (On as-is basis) | NLT 98.0% and NMT 102.0% | 99.54% |
| 5. | Potency | For information | 98.54 % |

Remarks: The sample complies /does not comply as per USP Specification.



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