

G24-1

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CERTIFICATE OF ANALYSIS OF WORKING STANDARD

| | | | |
|--------------------|---------------------------|--------------------------------|-------------|
| NAME OF PRODUCT | GEMCITABINE HYDROCHLORIDE | | |
| STANDARDIZED BY | Self | MFG. / STANDARDIZED DATE | 10/2016 |
| BATCH NO. / WS NO. | CS0090 | RE-TEST / USE BEFORE DATE | 09/2017 |
| SAMPLE QUANTITY | 500mg | PRIMARY LOT NO. / TRACEABILITY | H01101/ USP |

| S. No. | Tests | Specifications | Results |
|--------|---|--|--|
| 1. | Description | White to off-white solid. | White solid. |
| 2. | Identification A: By IR B: By Chloride test | The IR absorption spectrum of the sample shall be concordant with that of the Gemcitabine Hydrochloride USP with standard spectrum. A white curdy precipitate should be form. | The IR absorption spectrum of the sample concordant with that of the Gemcitabine Hydrochloride USP with standard spectrum. A white curdy precipitate is formed. |
| 3. | Assay (on as is basis) | Not less than 97.5% and Not more than 101.5% of Gemcitabine Hydrochloride. | 100.0% |

REMARKS: The sample can be used as working standard for the specified period only.

Analyzed By: Deepshikha
Designation : QC Chemist
Date : 08/10/2016

Approved by: Nishu Pal
Designation : QA Manager
Date : 08/10/2016



VMG Pharmaceuticals Pvt. Ltd.

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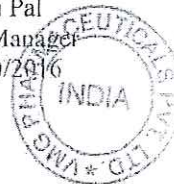
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