1. **Objective:**

The objective of this summary report is to certify the Method Validation of Bacterial Endotoxin test for Paclitaxel at Jodas Expoim Pvt. Ltd

1. **Qualification Procedure:**

As a part of Method Validation of Bacterial Endotoxin test for Paclitaxel the following tests were performed as per the general studies protocol and observations made are as follows.

The Following batches were used in performing the tests mentioned in the qualification procedure

1. GI-E20140
2. GI-E20141
3. GI-E20142
4. **Determination of maximum valid dilution:**

Maximum Valid non-interfering dilution (MVD) for Paclitaxel was determined by using the below formula,

|  |  |
| --- | --- |
| **MVD =** | Endotoxin limit X Concentration of Sample solution |
| Lysate sensitivity ( λ ) |

Where λ = Labeled sensitivity of Lysate (0.03 EU / mL)

Endotoxin Limit = NMT 0.4 EU/mg

Volume of LRW added: 1 mL

Concentration of the test solution is found to be 100 mg/mL

MVD was determined for all the batches and found to be 1333. Hence the maximum allowed non-interfering dilution is 1333.

* **Preparation of Solutions:**
* CSE, Lysate and sample solutions were prepared for all the three batches twice as given in annexure - 3 and used one set of the three batches for Screening for interference test and the other set of three batches for Inhibition & enhancement test.
* Quantity of sample taken: 100mg (Consider the tube as “A”)

Batch No’s.: GI-E20140

GI-E20141

GI-E20142

* Quantity of LRW added in tube A: 1mL
  + Proceeded for further dilutions as per the given table for screening of interference:
  + **Batch No.: GI-E20140**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tube No.** | **Vol. of sample taken** | **Vol. of LRW added** | **Obtained dilution** | **MVD** |
| B | 1mL from Tube No. A | 4.20 mL | 1:5.20 | MVD/256 |
| C | 1 mL from Tube No. B | 1 mL | 1:10.41 | MVD/128 |
| D | 1 mL from Tube No. C | 1 mL | 1:20.83 | MVD/64 |
| E | 1 mL from Tube No. D | 1 mL | 1:41.66 | MVD/32 |
| F | 1 mL from Tube No. E | 1 mL | 1:83.31 | MVD/16 |
| G | 1 mL from Tube No. F | 1 mL | 1:166.62 | MVD/8 |
| H | 1 mL from Tube No. G | 1 mL | 1:333.25 | MVD/4 |
| I | 1 mL from Tube No. H | 1 mL | 1:666.5 | MVD/2 |
| J | 1 mL from Tube No. I | 1 mL | 1:1333 | MVD |

* + **Batch No.: GI-E20141**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tube No.** | **Vol. of sample taken** | **Vol. of LRW added** | **Obtained dilution** | **MVD** |
| B | 1mL from Tube No. A | 4.20 mL | 1:5.20 | MVD/256 |
| C | 1 mL from Tube No. B | 1 mL | 1:10.41 | MVD/128 |
| D | 1 mL from Tube No. C | 1 mL | 1:20.83 | MVD/64 |
| E | 1 mL from Tube No. D | 1 mL | 1:41.66 | MVD/32 |
| F | 1 mL from Tube No. E | 1 mL | 1:83.31 | MVD/16 |
| G | 1 mL from Tube No. F | 1 mL | 1:166.62 | MVD/8 |
| H | 1 mL from Tube No. G | 1 mL | 1:333.25 | MVD/4 |
| I | 1 mL from Tube No. H | 1 mL | 1:666.5 | MVD/2 |
| J | 1 mL from Tube No. I | 1 mL | 1:1333 | MVD |

* + **Batch No.: GI-E20142**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tube No.** | **Vol. of sample taken** | **Vol. of LRW added** | **Obtained dilution** | **MVD** |
| B | 1mL from Tube No. A | 4.20 mL | 1:5.20 | MVD/256 |
| C | 1 mL from Tube No. B | 1 mL | 1:10.41 | MVD/128 |
| D | 1 mL from Tube No. C | 1 mL | 1:20.83 | MVD/64 |
| E | 1 mL from Tube No. D | 1 mL | 1:41.66 | MVD/32 |
| F | 1 mL from Tube No. E | 1 mL | 1:83.31 | MVD/16 |
| G | 1 mL from Tube No. F | 1 mL | 1:166.62 | MVD/8 |
| H | 1 mL from Tube No. G | 1 mL | 1:333.25 | MVD/4 |
| I | 1 mL from Tube No. H | 1 mL | 1:666.5 | MVD/2 |
| J | 1 mL from Tube No. I | 1 mL | 1:1333 | MVD |

* + Proceeded for further dilutions as per the given table for Inhibition & Enhancement:
  + **Batch No.: GI-E20140**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tube No.** | **Vol. of sample taken** | **Vol. of LRW added** | **Obtained dilution** | **MVD** |
| B | 1mL from Tube No. A | 4.20 mL | 1:5.20 | MVD/256 |
| C | 1 mL from Tube No. B | 1 mL | 1:10.41 | MVD/128 |
| D | 1 mL from Tube No. C | 1 mL | 1:20.83 | MVD/64 |
| E | 1 mL from Tube No. D | 1 mL | 1:41.66 | MVD/32 |
| F | 1 mL from Tube No. E | 1 mL | 1:83.31 | MVD/16 |
| G | 1 mL from Tube No. F | 1 mL | 1:166.62 | MVD/8 |
| H | 1 mL from Tube No. G | 1 mL | 1:333.25 | MVD/4 |
| I | 1 mL from Tube No. H | 1 mL | 1:666.5 | MVD/2 |
| J | 1 mL from Tube No. I | 1 mL | 1:1333 | MVD |

* + **Batch No.: GI-E20141**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tube No.** | **Vol. of sample taken** | **Vol. of LRW added** | **Obtained dilution** | **MVD** |
| B | 1mL from Tube No. A | 4.20 mL | 1:5.20 | MVD/256 |
| C | 1 mL from Tube No. B | 1 mL | 1:10.41 | MVD/128 |
| D | 1 mL from Tube No. C | 1 mL | 1:20.83 | MVD/64 |
| E | 1 mL from Tube No. D | 1 mL | 1:41.66 | MVD/32 |
| F | 1 mL from Tube No. E | 1 mL | 1:83.31 | MVD/16 |
| G | 1 mL from Tube No. F | 1 mL | 1:166.62 | MVD/8 |
| H | 1 mL from Tube No. G | 1 mL | 1:333.25 | MVD/4 |
| I | 1 mL from Tube No. H | 1 mL | 1:666.5 | MVD/2 |
| J | 1 mL from Tube No. I | 1 mL | 1:1333 | MVD |

* + **Batch No.: GI-E20142**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tube No.** | **Vol. of sample taken** | **Vol. of LRW added** | **Obtained dilution** | **MVD** |
| B | 1mL from Tube No. A | 4.20 mL | 1:5.20 | MVD/256 |
| C | 1 mL from Tube No. B | 1 mL | 1:10.41 | MVD/128 |
| D | 1 mL from Tube No. C | 1 mL | 1:20.83 | MVD/64 |
| E | 1 mL from Tube No. D | 1 mL | 1:41.66 | MVD/32 |
| F | 1 mL from Tube No. E | 1 mL | 1:83.31 | MVD/16 |
| G | 1 mL from Tube No. F | 1 mL | 1:166.62 | MVD/8 |
| H | 1 mL from Tube No. G | 1 mL | 1:333.25 | MVD/4 |
| I | 1 mL from Tube No. H | 1 mL | 1:666.5 | MVD/2 |
| J | 1 mL from Tube No. I | 1 mL | 1:1333 | MVD |

* **Screening for Interference:** This test is done on three batches and the de-pyrogenated test tubes are labeled, arranged in test tube stand and added LRW , sample, CSE and Lysate as per following tables in duplicate.

**Batch No.: GI-E20140**

Sample pH verification:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Description** | **LRW in µL** | **CSE in µL** | **Sample in µL** | **Lysate in µL** | **pH (mixture of the Lysate and sample solution)** | **Result** |
| A | NPC(MVD/128) | 50 | -- | 50 (MVD/256) | 100 | 6.96 | Pass |
| B | NPC(MVD/64) | 50 | -- | 50 (MVD/128) | 100 | 6.92 | Pass |
| C | NPC(MVD/32) | 50 | -- | 50 (MVD/64) | 100 | 6.86 | Pass |
| D | NPC(MVD/16) | 50 | -- | 50 (MVD/32) | 100 | 6.85 | Pass |
| E | NPC(MVD/8) | 50 | -- | 50 (MVD/16) | 100 | 6.82 | Pass |
| F | NPC(MVD/4) | 50 | -- | 50 (MVD/8) | 100 | 6.84 | Pass |
| G | NPC(MVD/2) | 50 | -- | 50 (MVD/4) | 100 | 6.84 | Pass |
| H | NPC(MVD) | 50 | -- | 50 (MVD/2) | 100 | 6.84 | Pass |

Determination of Non Inhibitory dilution (NID)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Description** | **LRW in µL** | **CSE in µL** | **Sample in µL** | **Lysate in µL** | **Result** |
| 1 & 2 | Negative control | 100 | NA | NA | 100 | – – |
| 3 & 4 | NPC (MVD/128) | 50 | -- | 50 (MVD/256) | 100 | – – |
| 5 & 6 | PPC (MVD/128) | -- | 50 ( 4 | 50 (MVD/256) | 100 | – – |
| 7 & 8 | NPC (MVD/64) | 50 | -- | 50 (MVD/128) | 100 | – – |
| 9 & 10 | PPC (MVD/64) | -- | 50 ( 4 | 50 (MVD/128) | 100 | – – |
| 11 & 12 | NPC (MVD/32) | 50 | -- | 50 (MVD/64) | 100 | – – |
| 13 & 14 | PPC (MVD/32) | -- | 50 ( 4 | 50 (MVD/64) | 100 | – – |
| 15 & 16 | NPC (MVD/16) | 50 | -- | 50 (MVD/32) | 100 | – – |
| 17 & 18 | PPC (MVD/16) | -- | 50 ( 4 | 50 (MVD/32) | 100 | – – |
| 19 & 20 | NPC (MVD/8) | 50 | -- | 50 (MVD/16) | 100 | – – |
| 21 & 22 | PPC (MVD/8) | -- | 50 ( 4 | 50 (MVD/16) | 100 | – – |
| 23 & 24 | NPC (MVD/4) | 50 | -- | 50 (MVD/8) | 100 | – – |
| 25 & 26 | PPC (MVD/4) | -- | 50 ( 4 | 50 (MVD/8) | 100 | – – |
| 27 & 28 | NPC (MVD/2) | 50 | -- | 50 (MVD/4) | 100 | – – |
| 29 & 30 | PPC (MVD/2) | -- | 50 ( 4 | 50 (MVD/4) | 100 | + + |
| 31 & 32 | NPC (MVD) | 50 | -- | 50 (MVD/2) | 100 | – – |
| 33 & 34 | PPC (MVD) | -- | 50 ( 4 | 50 (MVD/2) | 100 | + + |

NPC: Negative product control +: Gel clot formed

PPC: Positive product control - : Gel clot not formed.

After getting the results, MVD/4 dilution is showing PPC of positive result and sample (NPC) result showing negative result. The Non interference Dilution (NID) is MVD/4.

**Batch No.: GI-E20141**

Sample pH verification:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Description** | **LRW in µL** | **CSE in µL** | **Sample in µL** | **Lysate in µL** | **pH (mixture of the Lysate and sample solution)** | **Result** |
| A | NPC(MVD/128) | 50 | -- | 50 (MVD/256) | 100 | 6.96 | Pass |
| B | NPC(MVD/64) | 50 | -- | 50 (MVD/128) | 100 | 6.92 | Pass |
| C | NPC(MVD/32) | 50 | -- | 50 (MVD/64) | 100 | 6.86 | Pass |
| D | NPC(MVD/16) | 50 | -- | 50 (MVD/32) | 100 | 6.85 | Pass |
| E | NPC(MVD/8) | 50 | -- | 50 (MVD/16) | 100 | 6.82 | Pass |
| F | NPC(MVD/4) | 50 | -- | 50 (MVD/8) | 100 | 6.84 | Pass |
| G | NPC(MVD/2) | 50 | -- | 50 (MVD/4) | 100 | 6.84 | Pass |
| H | NPC(MVD) | 50 | -- | 50 (MVD/2) | 100 | 6.84 | Pass |

Determination of Non Inhibitory dilution (NID

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Description** | **LRW in µL** | **CSE in µL** | **Sample in µL** | **Lysate in µL** | **Result** |
| \* & \* | Negative control | 100 | NA | NA | 100 | – – |
| 35 & 36 | NPC (MVD/128) | 50 | -- | 50 (MVD/256) | 100 | – – |
| 37 & 38 | PPC (MVD/128) | -- | 50 ( 4 | 50 (MVD/256) | 100 | – – |
| 39 & 40 | NPC (MVD/64) | 50 | -- | 50 (MVD/128) | 100 | – – |
| 41 & 42 | PPC (MVD/64) | -- | 50 ( 4 | 50 (MVD/128) | 100 | – – |
| 43 & 44 | NPC (MVD/32) | 50 | -- | 50 (MVD/64) | 100 | – – |
| 45 & 46 | PPC (MVD/32) | -- | 50 ( 4 | 50 (MVD/64) | 100 | – – |
| 47 & 48 | NPC (MVD/16) | 50 | -- | 50 (MVD/32) | 100 | – – |
| 49 & 50 | PPC (MVD/16) | -- | 50 ( 4 | 50 (MVD/32) | 100 | – – |
| 51 & 52 | NPC (MVD/8) | 50 | -- | 50 (MVD/16) | 100 | – – |
| 53 & 54 | PPC (MVD/8) | -- | 50 ( 4 | 50 (MVD/16) | 100 | – – |
| 55 & 56 | NPC (MVD/4) | 50 | -- | 50 (MVD/8) | 100 | – – |
| 57 & 58 | PPC (MVD/4) | -- | 50 ( 4 | 50 (MVD/8) | 100 | – – |
| 59 & 60 | NPC (MVD/2) | 50 | -- | 50 (MVD/4) | 100 | – – |
| 61 & 62 | PPC (MVD/2) | -- | 50 ( 4 | 50 (MVD/4) | 100 | + + |
| 63 & 64 | NPC (MVD) | 50 | -- | 50 (MVD/2) | 100 | – – |
| 65 & 66 | PPC (MVD) | -- | 50 ( 4 | 50 (MVD/2) | 100 | + + |

NPC: Negative product control +: Gel clot formed

PPC: Positive product control - : Gel clot not formed.

After getting the results, MVD/4 dilution is showing PPC of positive result and sample (NPC) result showing negative result. The Non interference Dilution (NID) is MVD/4.

**Batch No.: GI-E20142**

Sample pH verification:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Description** | **LRW in µL** | **CSE in µL** | **Sample in µL** | **Lysate in µL** | **pH (mixture of the Lysate and sample solution)** | **Result** |
| A | NPC(MVD/128) | 50 | -- | 50 (MVD/256) | 100 | 6.96 | Pass |
| B | NPC(MVD/64) | 50 | -- | 50 (MVD/128) | 100 | 6.92 | Pass |
| C | NPC(MVD/32) | 50 | -- | 50 (MVD/64) | 100 | 6.86 | Pass |
| D | NPC(MVD/16) | 50 | -- | 50 (MVD/32) | 100 | 6.85 | Pass |
| E | NPC(MVD/8) | 50 | -- | 50 (MVD/16) | 100 | 6.82 | Pass |
| F | NPC(MVD/4) | 50 | -- | 50 (MVD/8) | 100 | 6.84 | Pass |
| G | NPC(MVD/2) | 50 | -- | 50 (MVD/4) | 100 | 6.84 | Pass |
| H | NPC(MVD) | 50 | -- | 50 (MVD/2) | 100 | 6.84 | Pass |

Determination of Non Inhibitory dilution (NID)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Description** | **LRW in µL** | **CSE in µL** | **Sample in µL** | **Lysate in µL** | **Result** |
| \* & \* | Negative control | 100 | NA | NA | 100 | – – |
| 67 & 68 | NPC (MVD/128) | 50 | -- | 50 (MVD/256) | 100 | – – |
| 69 & 70 | PPC (MVD/128) | -- | 50 ( 4 | 50 (MVD/256) | 100 | – – |
| 71 & 72 | NPC (MVD/64) | 50 | -- | 50 (MVD/128) | 100 | – – |
| 73 & 74 | PPC (MVD/64) | -- | 50 ( 4 | 50 (MVD/128) | 100 | – – |
| 75 & 76 | NPC (MVD/32) | 50 | -- | 50 (MVD/64) | 100 | – – |
| 77 & 78 | PPC (MVD/32) | -- | 50 ( 4 | 50 (MVD/64) | 100 | – – |
| 79 & 80 | NPC (MVD/16) | 50 | -- | 50 (MVD/32) | 100 | – – |
| 81 & 82 | PPC (MVD/16) | -- | 50 ( 4 | 50 (MVD/32) | 100 | – – |
| 83 & 84 | NPC (MVD/8) | 50 | -- | 50 (MVD/16) | 100 | – – |
| 85 & 86 | PPC (MVD/8) | -- | 50 ( 4 | 50 (MVD/16) | 100 | – – |
| 87 & 88 | NPC (MVD/4) | 50 | -- | 50 (MVD/8) | 100 | – – |
| 89 & 90 | PPC (MVD/4) | -- | 50 ( 4 | 50 (MVD/8) | 100 | – – |
| 91 & 92 | NPC (MVD/2) | 50 | -- | 50 (MVD/4) | 100 | – – |
| 93 & 94 | PPC (MVD/2) | -- | 50 ( 4 | 50 (MVD/4) | 100 | + + |
| 95 & 96 | NPC (MVD) | 50 | -- | 50 (MVD/2) | 100 | – – |
| 97 & 98 | PPC (MVD) | -- | 50 ( 4 | 50 (MVD/2) | 100 | + + |

NPC: Negative product control +: Gel clot formed

PPC: Positive product control - : Gel clot not formed.

After getting the results, MVD/4 dilution is showing PPC of positive result and sample (NPC) result showing negative result. The Non interference Dilution (NID) is MVD/4.

* **Inhibition and Enhancement test:**
* Maximum allowed dilution is selected, as non-interfering dilution during screening for interference.
* The test tubes were labeled and arranged in test tube stand and LRW, sample, CSE and Lysate were added as per following table.

**Batch No.: GI-E20140**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Solution** | | **LRW in L** | **CSE in L** | **Sample in L (MVD/\_\_)** | **Lysate in L** | **Result** |
| 1 - 4 | A (Sample Solution) | -- | 50 | -- | 50 | 100 | – – – – |
| 5 - 8 | B  (Sample Solution with CSE) | 2 | -- | 50 ( 4 | 50 | 100 | + + + + |
| 9 - 12 |  | -- | 50 ( 2 | 50 | 100 | + + + + |
| 13 - 16 | /2 | -- | 50 (  | 50 | 100 | – – – – |
| 17 - 20 | /4 | -- | 50 (  | 50 | 100 | – – – – |
| 21 – 24 | C  (LRW  with CSE) | 2 | 50 | 50 ( 4 | -- | 100 | + + + + |
| 25 - 28 |  | 50 | 50 (2  | -- | 100 | + + + + |
| 29 - 32 | /2 | 50 | 50 (  | -- | 100 | – – – – |
| 33 - 36 | /4 | 50 | 50 (  | -- | 100 | – – – – |
| 37 - 40 | D (NC) | -- | 100 | -- | -- | 100 | – – – – |

* The Geometric mean Calculated for solutions B and C is found to be 0.03 EU/mL.
* The Selected dilution for routine BET test is **MVD/2**.

**Batch No.: GI-E20141**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Solution** | | **LRW in L** | **CSE in L** | **Sample in L (MVD/\_\_)** | **Lysate in L** | **Result** |
| 41-44 | A (Sample Solution) | -- | 50 | -- | 50 | 100 | – – – – |
| 45-48 | B  (Sample Solution with CSE) | 2 | -- | 50 ( 4 | 50 | 100 | + + + + |
| 49-52 |  | -- | 50 ( 2 | 50 | 100 | + + + + |
| 53-56 | /2 | -- | 50 (  | 50 | 100 | – – – – |
| 57-60 | /4 | -- | 50 (  | 50 | 100 | – – – – |
| For tube numbering refer Batch no.:GI-E20140 | C  (LRW  with CSE) | 2 | 50 | 50 ( 4 | -- | 100 | For results refer Batch no.: GI-E20140 |
|  | 50 | 50 (2  | -- | 100 |
| /2 | 50 | 50 (  | -- | 100 |
| /4 | 50 | 50 (  | -- | 100 |
| D (NC) | -- | 100 | -- | -- | 100 |

* The Geometric mean Calculated for solutions B and C is found to be 0.03 EU/mL.
* The Selected dilution for routine BET test is **MVD/2.**

**Batch No.: GI-E20142**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Tube No.** | **Solution** | | **LRW in L** | **CSE in L** | **Sample in L (MVD/\_\_)** | **Lysate in L** | **Result** |
| 61-64 | A (Sample Solution) | -- | 50 | -- | 50 | 100 | – – – – |
| 65-68 | B  (Sample Solution with CSE) | 2 | -- | 50 ( 4 | 50 | 100 | + + + + |
| 69-72 |  | -- | 50 ( 2 | 50 | 100 | + + + + |
| 73-76 | /2 | -- | 50 (  | 50 | 100 | – – – – |
| 77-80 | /4 | -- | 50 (  | 50 | 100 | – – – – |
| For tube numbering refer Batch no.: GI-E20140 | C  (LRW  with CSE) | 2 | 50 | 50 ( 4 | -- | 100 | For results refer Batch no.: GI-E20140 |
|  | 50 | 50 (2  | -- | 100 |
| /2 | 50 | 50 (  | -- | 100 |
| /4 | 50 | 50 (  | -- | 100 |
| D (NC) | -- | 100 | -- | -- | 100 |

* The Geometric mean Calculated for solutions B and C is found to be 0.03 EU/mL.
* The Selected dilution for routine BET test is **MVD/2**.
* Solution” A" and "D" showed negative result.
* The geometric mean of Solution B and Solution C was calculated and met the acceptance criteria of not more than 2λ and not less than λ/2.

1. **Data review:**

All the test results and attachments were reviewed and found to be satisfactory.

1. **Exception/deviation/Discrepancy:**

No deviation/discrepancy was observed during the Method Validation of Bacterial Endotoxin test for Paclitaxel.

1. **Conclusion:**

After reviewing the results, it can be concluded that

* The endpoints are within ± 2 fold variation of λ (i.e. Sensitivity of lysate: 0.03 EU/mL). So the label claim of lysate is verified.
* PPC of MVD/4, MVD/2 and MVD shown firm gel formation, NPC of MVD/4, MVD/2 and MVD shown no gel formation that indicates that no Inhibition and Enhancement. So the maximum valid non-interfering dilution MVD/4 was selected for validation.

End points are within ± 2 fold of the lysate sensitivity, Sample and negative controls are showing no gel clot formation and hence, the sample is validated at MVD/4. When the sample checked at MVD/4 the Endotoxin Level is less than 0.029 USP EU/mg.

* Hence, it is decided that routine Bacterial Endotoxin test of Paclitaxel shall be carried out at MVD/2 by Gel clot method.

1. **Recommendations:**

It is recommended to carry out BET at MVD/2 dilution for routine analysis for Paclitaxel

1. **Validated parameters:**

* Not Applicable.

|  |  |  |  |
| --- | --- | --- | --- |
| **Department** | **Name** | **Designation** | **Signature /Date** |
| **Prepared by** | | | |
| Quality Control (Microbiology) |  |  |  |
| **Reviewed by** | | | |
| QA-Validation |  |  |  |
| Quality Control (Microbiology) |  |  |  |
| **Approved by** | | | |
| Quality Assurance |  |  |  |