

MICROBIOLOGY DEPARTMENT

#### STANDARD OPERATING PROCEDURE

| Department: Microbiology  | SOP No.:        |
|---|-----------------|
| Title: Microbiological Monitoring of Drain Traps in Injection Block | Effective Date: |
| Supersedes: Nil   | Review Date:    |
| Issue Date:   | Page No.:       |

#### **1.0 OBJECTIVE:**

To lay down a procedure for Microbiological Monitoring of Drain Traps.

#### **2.0 SCOPE:**

This SOP is applicable for Microbiological Monitoring of Drain Traps in Injection Block of Quality Control Area.

#### **3.0 RESPONSIBILITY:** Officer / Executive - Microbiologist

## 4.0 ACCOUNTABILITY:

Head – QC

#### 5.0 **PROCEDURE:**

#### 5.1 SAMPLING:

- **5.1.1** Take the required quantity of swab stick and aseptically add sterile 10 ml of 0.9% saline solution, in each of individual swab tubes and kept in SS container.
- **5.1.2** After Cleaning & Sanitization take swab stick and rub on the Drain Traps in unidirectional to cover approx 5x5 cm area which is to be monitored. During swabbing swab should not be overlapped, it should be discontinuous. After sampling sanitize the sampled area using filtered 70% IPA.
- **5.1.3** Label the sample swab with drain point number, date and time and after this transfer the sample to Microbiology Laboratory for further analysis.



#### 5.2 TEST FOR SPECIFIED MICROORGANISMS:

#### 5.2.1 Pretreatment of Sample:

- **5.2.1.1** Filter 10 ml of swab sample and insert in 90ml Soyabean Casein Digest Broth Medium or soya lecithin Broth.
- **5.2.1.2** Incubate the medium at 30-35<sup>o</sup>C for 18-24 hrs.
- 5.2.2 Test for Escherichia coli:



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- **5.2.2.1** Shake the tube and transfer 1 ml of pretreated sample (SCM) to 100 ml of Maconkey Broth and incubate 42 to 44<sup>o</sup>C for 24 to 48 hrs.
- **5.2.2.2** Streak a portion from MacConkey broth on the surface of MacConkey Agar media and incubate 30 to 35<sup>o</sup>C for 18 to 72 hrs.
- **5.2.2.3** Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of the E. coli.
- **5.2.2.4** Run Positive and Negative Control with test.

#### 5.2.3 Test for Salmonella spp.:

- **5.2.3.1** Shake the tube and transfer 0.1 ml of pretreated sample to 10 ml of Rappaport Vassiliadis Salmonella Enrichment Broth and incubate at 30 to 35<sup>o</sup>C for 18 to 24 hrs.
- **5.2.3.2** Streak a portion from the Rappaport Vassiliadis Salmonella Enrichment Broth on surface of Xylose Lysine Deoxycholate Agar Medium and incubate 30 to 35<sup>o</sup>C for 18 to 48 hrs.
- **5.2.3.3** Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of the Salmonella spp.
  - **5.2.3.4** Run Positive and Negative Control with test.

#### 5.2.4 Test for Pseudomonas aeruginosa:

- **5.2.4.1** Shake the tube and streak one loop full pretreated sample (SCM) on to the plate of Cetrimide Agar Medium and incubate 30 to 35<sup>o</sup>C for 18 to 72 hrs.
- **5.2.4.2** Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of the Pseudomonas aeruginosa.
- **5.2.4.3** Oxidase Test: If growth of suspected colonies occurs, place suspected colony on the oxidase disc or paper strips or discs that previously had been impregnated with N, N-dimethyl-p- phenylenediamine dihydrochloride. If there is no development of a pink color, changing to purple color, the sample meets the requirements of the test for absence of *Pseudomonas aeruginosa*.
- **5.2.4.4** Run Negative Control with test.
- 5.2.5 Test for Staphylococcus aureus:



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- **5.2.5.1** Shake the tube and streak one loop full pretreated sample (SCM) on to the plate of Mannitol Salt Agar Medium and incubate at 30 to 35<sup>o</sup>C for 18 to 72 hrs.
- **5.2.5.2** Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of the Staphylococcus aureus.
- 5.2.5.3 Run Negative Control with test.

#### **5.2.6** Test for Bile-Tolerant Gram-Negative Bacteria (Enterobacteria):

- **5.2.6.1** Transfer 1 ml of sample to 100 ml Enterobacteria Enrichment Broth Mossel. Incubate the medium at 30 to 35<sup>o</sup>C for 24 to 48 hrs.
- **5.2.6.2** After Incubation, Subculture on the plate of Violet Red Bile Glucose Agar and incubate at 30 to 35<sup>o</sup>C for 18 to 24 hrs.
- **5.2.6.3** Upon examination, if none of the colonies confirm to the description given in Table-1, the sample meets the requirements for the absence of Enterobacteria.
- **5.2.6.4** Run Negative Control with test.
- **5.2.7** Frequency of Monitoring: Each drain point should be monitored at fortnightly basis in each month. If Monitoring of Drain is due on holiday or weekly off in such case monitoring should be performed one day before or next working day including scheduled drain point monitoring.

#### 5.2.8 ACCEPTANCE CRITERIA:

**Specified Microorganisms** – Escherichia coli, Salmonella spp., Pseudomonas aeruginosa, Staphylococcus aureus, Bile-Tolerant Gram-Negative Bacteria (Enterobacteria) should be absent.

**5.2.9** Drain point sampling shall be done as per Drain Point Sampling Schedule as shown in **Annexure-III**, Titled **"Drain Point Sampling Schedule"**.

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#### TABLE-1

| Specified<br>Microorganism                       | Media Name  | Positive Growth<br>Characteristics                     | Gram Staining<br>Characteristics |
|--|---|--|----------------------------------|
| E achi   | MacConkey Broth   | Medium colour turns to yellow.                         | Gram Nagativa Pod                |
| E. COII  | MacConkey Agar  | Pink/red coloured non-mucoid colonies.                 |                                  |
| Salmonella                                       | Rappaport Vassiliadis<br>Salmonella Enrichment<br>Broth               | Medium colour turns to reddish pink.                   | Gram Negative Rod                |
|  | Xylose lysine<br>Deoxycholate Agar                                    | Red colonies with or without black centers.            |                                  |
| Pseudomonas<br>aeruginosa                        | Cetrimide Agar  | Greenish yellow colonies                               | Gram Negative Rod                |
| Staphylococcus<br>aureus                         | Mannitol Salt Agar  | Yellow colonies surrounded by yellow zones.            | Gram Positive<br>Cocci           |
| Bile Tolerant Gram<br>Negative<br>Enterobacteria | Enterobacteria Enrichment<br>Broth, Mossel<br>Violet Red Bile glucose | Medium colour turns to<br>yellow.<br>Pink/red colonies | Gram Negative                    |

#### 6.0 **REFERENCES:**

Drug and Cosmetic Act 1940, Schedule M

#### 7.0 ANNEXURES:

| ANNEXURE No.   | TITLE OF ANNEXURE  | FORMAT No. |
|----------------|--|------------|
| Annexure – I   | Sample Receipt and Analysis Record for Drain Swab Sample |            |
| Annexure – II  | Drain Sample Analysis Report                             |            |
| Annexure – III | Drain Point Sampling Schedule                            |            |

#### ENCLOSURES: SOP Training Record

#### 8.0 **DISTRIBUTION:**

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- Controlled Copy No. 01 Quality Assurance Department
  - Controlled Copy No. 02 Quality Control Department
  - Master Copy Quality Assurance Department



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#### 9.0 ABBREVIATIONS:

| μm   | Micrometer                      |
|------|---------------------------------|
| cfu  | Colony Forming Unit             |
| CTA  | Cetrimide Agar                  |
| Hrs. | Hours                           |
| IPA  | Isopropyl Alcohol               |
| LAF  | Laminar Air Flow                |
| ml   | Milliliter                      |
| No.  | Number                          |
| QA   | Quality Assurance               |
| QC   | Quality Control                 |
| SCA  | Soyabean Casein Digest Agar     |
| SOP  | Standard Operating Procedure    |
| XLA  | Xylose lysine Deoxycholate Agar |

#### **10.0 REVISION HISTORY:**

#### **CHANGE HISTORY LOG**

| Revision No. | Details of Changes | Reason for Change | Effective Date | Updated By |
|--------------|--------------------|-------------------|----------------|------------|
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#### ANNEXURE – I

| SAMPLE RECEIPT AND ANALYSIS RECORD FOR DRAIN SWAB SAMPLE |      |          |             |                          |                    |                  |                  | ·               |                             |                                |         |
|--|------|----------|-------------|--------------------------|--------------------|------------------|------------------|-----------------|-----------------------------|--------------------------------|---------|
| Date   | Area | Location | Drain<br>ID | Analytical<br>Report No. | Sample<br>Quantity | Sampling<br>Date | Analysis<br>Date | Release<br>Date | Done By<br>(Sign &<br>Date) | Checked<br>By (Sign<br>& Date) | Remarks |
|  |      |          |             |                          |                    |                  |                  |                 |                             |                                |         |
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# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

|  |  | STANDARD                       | OPERATING                                       | PROCE  | DURE                            |                     |                         |
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| Department: Micro  | biology  |                                |   |  | SOP N                           | 0.:                 |                         |
| Fitle: Microbiologic   | cal Monitoring   | of Drain Traps                 | in Injection Blo                                | ock  | Effecti                         | ve Date:            |                         |
| Supersedes: Nil  |  |                                |   |  | Review                          | <b>Date:</b>        |                         |
| ssue Date:   |  |                                |   |  | Page N                          | 0.:                 |                         |
|  |  | AN<br>DRAIN SAMP               | NEXURE – II<br>LE ANALYSI                       | S REPO   | RT                              |                     |                         |
| Date of Sampling   |  |                                |   |  |                                 |                     |                         |
| A. R. No   |  |                                |   |  |                                 |                     |                         |
| Sampling Points  |  |                                |   |  |                                 |                     |                         |
| Volume sampled   |  |                                |   |  |                                 |                     |                         |
| Date of Testing  |  |                                |   |  |                                 |                     |                         |
| Tested By  |  |                                |   |  |                                 |                     |                         |
| ſest   | : Test for Spe   | ecified Microor                | ganisms Da                                      | te of Te                                       | st:                             |                     |                         |
|  | nple:  |                                | -   |  |                                 |                     |                         |
| Enrichment of San  | -r   |                                |   |  |                                 |                     |                         |
| Enrichment of San<br>Test Method   | :  |                                |   |  |                                 |                     |                         |
| Enrichment of San<br>Test Method<br>Name of media  | :<br>: Soyabean Ca   | asein Digest Me                | dium or soya le                                 | ecithin br                                     | oth                             |                     |                         |
| Enrichment of San<br>Sest Method<br>Name of media<br>Volume of Sample  | :<br>: Soyabean Ca<br>: 1 ml                               | asein Digest Me                | dium or soya le<br>Ma                           | ecithin br<br>e <b>dia Ref</b> e               | oth<br>e <b>rence N</b> o       | ). <b>:</b>         |                         |
| Enrichment of San<br>Fest Method<br>Name of media<br>Volume of Sample<br>Incubator Temp.   | :<br>: Soyabean C<br>: 1 ml<br>: 30-35 <sup>0</sup> C for  | asein Digest Me<br>18 - 24 hrs | dium or soya le<br>Me<br>Incubatio              | ecithin br<br>edia Refe<br>n ID No             | oth<br>erence No                | <b>).:</b>          |                         |
| Enrichment of San<br>Fest Method<br>Name of media<br>Volume of Sample<br>ncubator Temp.<br>Date of Incubation                        | :<br>: Soyabean Ca<br>: 1 ml<br>: 30-35 <sup>0</sup> C for | asein Digest Me<br>18 - 24 hrs | dium or soya la<br>Ma<br>Incubatio<br>Date of O | ecithin br<br>edia Ref<br>n ID No<br>bservati  | oth<br>erence No<br>. :<br>on : | <b></b> :           |                         |
| Enrichment of San<br>Fest Method<br>Name of media<br>Volume of Sample<br>Incubator Temp.<br>Date of Incubation                       | :<br>: Soyabean C:<br>: 1 ml<br>: 30-35 <sup>0</sup> C for | asein Digest Me                | dium or soya le<br>Me<br>Incubatio<br>Date of O | ecithin br<br>edia Refe<br>n ID No<br>bservati | oth<br>erence No<br>. :<br>on : | Positive<br>control | <br>Negati<br>ve        |
| Enrichment of San<br>Fest Method<br>Name of media<br>Volume of Sample<br>Incubator Temp.<br>Date of Incubation<br>Sampling<br>Points | : Soyabean Ca<br>: 1 ml<br>: 30-35 <sup>0</sup> C for      | asein Digest Me                | dium or soya le<br>Me<br>Incubatio<br>Date of O | ecithin br<br>edia Refo<br>n ID No<br>bservati | oth<br>erence No<br>. :<br>on : | Positive<br>control | Negati<br>ve<br>control |

Remarks:



### PHARMA DEVILS MICROBIOLOGY DEPARTMENT

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| Department: Microbiology  |  |                             |                               |  |                                    | SOP No.:                      |                    |   |  |  |  |  |
| <b>Fitle:</b> Microbiological Monit   | oring of Drain   | n Traps in I                | njection B                    | lock                                   | Effective Date:<br>Review Date:    |                               |                    |   |  |  |  |  |
| Supersedes: Nil   |  |                             |                               |  |                                    |                               |                    |   |  |  |  |  |
| Issue Date:   |  |                             |                               |  | Page N                             | 0.:                           |                    |   |  |  |  |  |
| 1.0 Test for <i>Escherich</i><br>(I) Date :<br>Name of media : M<br>Incubation Temp.<br>Date of Incubation  | <i>nia coli</i> :<br>acConkey Bro<br>: 42-44 <sup>0</sup> C<br>:   | oth<br>for 24 -48           | N<br>hrs                      | Iedia Refe<br>Date                     | erence No<br>Incuba<br>e of Obser  | .:<br>ator ID No.<br>rvation: |                    |   |  |  |  |  |
| Sampling Points   |  |                             |                               |  | Positiv<br>contro                  |                               | ve N<br>bl         | Negativ<br>e<br>control   |  |  |  |  |
|   |  |                             |                               |  |                                    |                               |                    |   |  |  |  |  |
| Observation         (II) Date:         Name of Media         : MacC         Incubation Temp.:         30-35 <sup>(1)</sup> Date of Incubation:  | onkey Agar<br>C for 18 - 72  | hrs                         | l<br>Iu<br>D                  | Iedia Refe<br>icubator I               | rence No<br>D No. :                | :                             |                    |   |  |  |  |  |
| Observation         (II) Date:         Name of Media : MacC         Incubation Temp.: 30-35 <sup>(1)</sup> Date of Incubation:         .         Sampling Points  | onkey Agar<br>C for 18 - 72  | hrs                         |                               | Iedia Refe<br>icubator I<br>ate of Obs | erence No<br>D No. :<br>servation. | :<br>. :<br>P<br>c            | <br>Positiv        | e Negati<br>l ve<br>contro  |  |  |  |  |
| Observation         (II) Date:         Name of Media       : MacC         Incubation Temp.:       30-35°         Date of Incubation:  | onkey Agar<br>C for 18 - 72  | hrs                         |                               | Iedia Refe<br>icubator I<br>ate of Obs | erence No<br>D No. :<br>servation  | :<br>. :<br>P<br>c            | Positiv<br>contro  | <br>e Negati<br>l ve<br>contro<br>l   |  |  |  |  |
| Observation         (II) Date:         Name of Media       : MacC         Incubation Temp.:       30-35°         Date of Incubation:       .         Sampling Points       .         Observation       .         Remarks:       .         2.0 Test for Salmonella s       .         (I) Date       .         Name of Media: Rappapor       .         Incubation Temp. :       30-35°         Date of Incubation :       . | onkey Agar<br>PC for 18 - 72   | hrs<br><br>Enrichmen<br>hrs | N<br>II<br>D<br><br>t Broth M | Iedia Refe<br>ncubator I<br>ate of Obs | erence No<br>D No. :<br>servation. | :                             | Positiv<br>contro  | e Negati<br>l ve<br>contro<br>l   |  |  |  |  |
| Observation         (II) Date:  | onkey Agar<br>C for 18 - 72<br>PC for 18 - 72<br>pp:<br>t Vassialiadis<br>C for 18 - 24  | hrs<br><br>Enrichmen<br>hrs | N<br>Iu<br>D<br><br>t Broth N | Iedia Refe<br>ate of Obs               | erence No<br>D No. :<br>servation. | :                             | Positiv<br>Positiv | <br>e Negati<br>l ve<br>contro<br>l   |  |  |  |  |
| Observation         (II) Date:         Name of Media : MacC         Incubation Temp.: 30-35 <sup>(1)</sup> Date of Incubation:         Sampling Points         Observation         Remarks:         2.0 Test for Salmonella s         (I) Date         Name of Media: Rappapor         Incubation Temp. : 30-35 <sup>(2)</sup> Date of Incubation :         Sampling Points   | onkey Agar<br>C for 18 - 72<br>PC for 18 - 72<br>value of the second se | hrs<br><br>Enrichmen<br>hrs | N<br>In<br>D<br><br>t Broth N | Iedia Refe<br>ncubator I<br>ate of Obs | erence No<br>D No. :<br>servation. | :                             | ive rol            | <ul> <li>Negati</li> <li>ve</li> <li>contro</li> <li>1</li> <li></li> </ul> |  |  |  |  |

Name of media: Xylose Lysine Deoxycholate Agar Media Reference No.....



MICROBIOLOGY DEPARTMENT

|   |   | <b>STAND</b>                               |            | TRATINC                                    | ΡΡΟΟ               | FUIDE                                  |                     |                             |  |  |
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| Denartment · Microb   | viology                                 | STAND                                      |            |  | INUC               | SOP No.                                |                     |                             |  |  |
| Fitle: Microbiological Monitoring of Drain Traps in Injection Block<br>Supersedes: Nil        |   |  |            |  | Effective          | Date:                                  |                     |                             |  |  |
|   |   |  |            |  | Review I           | Date:                                  |                     |                             |  |  |
|   |   |  |            |  | Page No.           | :                                      |                     |                             |  |  |
| Incubation Temp.<br>Date of Incubation  | : 30-35 <sup>0</sup> C fo               | or 18 - 48 h                               | rs.        | Incubator ID No. :<br>Date of Observation. |                    |  |                     |                             |  |  |
| Sampling<br>Points<br>Observation   |   |  |            |  |                    |  | Positive<br>control | Negative<br>control         |  |  |
| Remarks:  |   |  |            |  |                    |  |                     |                             |  |  |
| 3.0 Test for <i>Pseud</i><br>Date :<br>Name of Med<br>Incubation Temp.:<br>Date of Incubation | ia: Cetrimid<br>30-35 <sup>0</sup> C fo | <i>ruginosa</i><br>le Agar<br>r 18 - 72 hr | °S         | Re<br>In<br>Da                             | eference<br>cubato | e No:<br>or ID No. :<br>Observation: : |                     |                             |  |  |
| Sampling Points   |   |  |            |  |                    |  | Positive<br>control | Negativ<br>e<br>control     |  |  |
| Observation   |   |  |            |  |                    |  |                     |                             |  |  |
| Name of Test Reag<br>Oxidase Test:  | gent: N, N-                             | dimethyl-p                                 | -phenyldia | amine dihyo                                | irochlo            | ride (Strips / l                       | Discs)<br>Date      |                             |  |  |
| Sampling Points   |   |  |            |  |                    |  | Positive<br>control | Negati<br>ve<br>contro<br>l |  |  |
| Observation   |   |  |            |  |                    |  |                     |                             |  |  |
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| Department: Microbiology   |   |                              |                                |                             | SOP No.:                       |                             |                                       |                               |  |  |
| Fitle: Microbiological Monitoring of Drain Traps in Injection Block         Supersedes: Nil         ssue Date: |   |                              |                                |                             |                                | Effective <b>E</b>          | Date:                                 |                               |  |  |
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| 4.0 Test for <i>Staphy</i><br>Date<br>Name of media: Mar<br>Incubation Temp.: 3<br>Date of Incubation.         | 5.  | Media<br>Incub<br>Date o     | a Refere<br>ator ID<br>of Obse | ence No<br>No. :<br>rvation |                                |                             |                                       |                               |  |  |
| Sampling Points  |   |                              |                                |                             |                                |                             | Positive<br>Control                   | Negativ<br>e<br>Control       |  |  |
| Observation  |   |                              |                                |                             |                                |                             |                                       |                               |  |  |
| Name of media: Entr<br>Incubation Temp. :  | <br>erobacteria<br>30 – 35 <sup>0</sup> C | Enrichmen<br>for 24 - 48     | t Broth Moss<br>hrs.           | el <b>Medi</b> a            | a Refere<br>Incub              | ence No<br>ator ID No       | • :                                   |                               |  |  |
| Date of Incubation.  | •••••                                     | ••••                         | 1                              |                             | Date of                        | of Observat                 | tion                                  |                               |  |  |
| Sampling Points  |   |                              |                                |                             |                                |                             | Positive<br>control                   | e Negat<br>ive<br>contr<br>ol |  |  |
| Observation  |   |                              |                                |                             |                                |                             |                                       |                               |  |  |
| (II) Date<br>Name of media: Vio<br>Incubation Temp.: 3<br>Date of Incubation.                                  | let Red Bil<br>80-35 <sup>0</sup> C for   | e Glucose A<br>r 18 - 24 hrs | Agar<br>3.                     | Media<br>Incub<br>Date o    | a Refere<br>ator ID<br>of Obse | ence No<br>No. :<br>rvation | · · · · · · · · · · · · · · · · · · · |                               |  |  |
| Sampling Points  |   |                              |                                |                             |                                |                             | Positiv<br>contro                     | re Neg<br>l ativ<br>e<br>cont |  |  |
| Observation  |   |                              |                                |                             |                                |                             |                                       | roi                           |  |  |



### PHARMA DEVILS MICROBIOLOGY DEPARTMENT

| STANDARD OPERATING PROCEDURE  |                 |  |  |  |
|---|-----------------|--|--|--|
| Department: Microbiology  | SOP No.:        |  |  |  |
| Title: Microbiological Monitoring of Drain Traps in Injection Block | Effective Date: |  |  |  |
| Supersedes: Nil   | Review Date:    |  |  |  |
| Issue Date:   | Page No.:       |  |  |  |

Remarks:

•••

. . . . . .

#### **CONCLUSIONS:**

| Tost Organism                 | Sampling Points |  |  |  |  |  |  |  |
|-------------------------------|-----------------|--|--|--|--|--|--|--|
| Test Organishi                |                 |  |  |  |  |  |  |  |
| E. coli                       |                 |  |  |  |  |  |  |  |
| Salmonella spp.               |                 |  |  |  |  |  |  |  |
| P. aeruginosa                 |                 |  |  |  |  |  |  |  |
| S. aureus                     |                 |  |  |  |  |  |  |  |
| Bile – Tolerant Gram Negative |                 |  |  |  |  |  |  |  |
| Bacteria (Enterobacteria)     |                 |  |  |  |  |  |  |  |

Comments:

- ve = No Growth with specified colony characteristic or specified negative response which indicate absence of specified organism (s) or Negative Test

**Remarks:** The above sample complies/does not comply as per IH specification.

Microbiologist: Date: Checked by: Date:



MICROBIOLOGY DEPARTMENT

| STANDARD OPERATING PROCEDURE  |                 |  |  |  |  |
|---|-----------------|--|--|--|--|
| Department: Microbiology  | SOP No.:        |  |  |  |  |
| Title: Microbiological Monitoring of Drain Traps in Injection Block | Effective Date: |  |  |  |  |
| Supersedes: Nil   | Review Date:    |  |  |  |  |
| Issue Date:   | Page No.:       |  |  |  |  |

#### ANNEXURE – III DRAIN POINT SAMPLING SCHEDULE

|                     | Sampling Point Location |                   |              | Frequency (Fortnightly) |              |    |    |    |    |  |  |
|---------------------|-------------------------|-------------------|--------------|-------------------------|--------------|----|----|----|----|--|--|
|                     |                         | Sampling Point ID | 1            | 2                       | 3            | 4  | 5  | 6  | 7  |  |  |
| Location            |                         | No.               | 9            | 10                      | 11           | 12 | 13 | 14 | 15 |  |  |
|                     |                         | 1101              | 16           | 17                      | 18           | 19 | 20 | 21 | 22 |  |  |
|                     |                         |                   | 23           | 24                      | 25           | 26 | 27 | 28 | 29 |  |  |
|                     | Production Janitor      |                   | N            |                         |              |    |    |    |    |  |  |
|                     | Dress Wash              |                   | N            |                         |              |    |    |    |    |  |  |
| First Floor         | Unit Preparation Room   |                   |              |                         |              |    |    |    |    |  |  |
| (Dry Powder)        | Equipment Washing       |                   |              |                         |              |    |    |    |    |  |  |
|                     | Vial Washing            |                   | $\checkmark$ |                         |              |    |    |    |    |  |  |
|                     | Packing Janitor Room    |                   |              |                         |              |    |    |    |    |  |  |
|                     | CIP/SIP room            |                   |              |                         |              |    |    |    |    |  |  |
|                     | MFG -1                  |                   |              |                         |              |    |    |    |    |  |  |
| First Floor         | MFG-2                   |                   |              |                         |              |    |    |    |    |  |  |
| (Three Piece)       | Unit preparation        |                   |              |                         |              |    |    |    |    |  |  |
|                     | Garment washing         |                   |              |                         |              |    |    |    |    |  |  |
|                     | Equipment washing       |                   |              | $\checkmark$            |              |    |    |    |    |  |  |
|                     | Janitor                 |                   |              |                         | $\checkmark$ |    |    |    |    |  |  |
|                     | Ampoules washing area   |                   |              |                         |              |    |    |    |    |  |  |
|                     | Autoclave area          |                   |              |                         | $\checkmark$ |    |    |    |    |  |  |
| <b>Ground Floor</b> | Equipment washing area  |                   |              |                         |              |    |    |    |    |  |  |
| (Ampoule            | Garment washing area    |                   |              |                         | $\checkmark$ |    |    |    |    |  |  |
| Line)               | CIP/SIP room            |                   |              |                         | $\checkmark$ |    |    |    |    |  |  |
|                     | Manufacturing area      |                   |              |                         | $\checkmark$ |    |    |    |    |  |  |
|                     | Terminal sterilizer     |                   |              |                         | $\checkmark$ |    |    |    |    |  |  |
|                     | Ampoules leak test      |                   |              |                         | $\checkmark$ |    |    |    |    |  |  |

Prepared By: Officer / Executive-QC (Sign & Date)

Checked By: Manager-QC (Sign & Date) Approved By: Head QA (Sign & Date)