

# SOMERSET THERAPEUTICS LIMITED

## DATA REPORT - SVP1 AND AMPOULE LINE EMS

## WASHING AND STERILIZATION AREA

|      | Date Time          | Temperature                                  | RH                                       | Diffrential Pressure  | Diffrential Pressure  | Diffrential Pressure  |
|------|--------------------|--|--|---|---|---|
| DD-N | MM-YYYY HH:MM:SS   | Washing and Sterilization Area<br>(NMT 30°C) | Washing and Sterilization Area (NMT 80%) | Washing and Sterilization Area<br>w.r.t Unit Preparation Room<br>(NLT 6 Pa) | Washing and Sterilization Area<br>w.r.t Ampoule Decartoning<br>Room (NLT 12 Pa) | Washing and Sterilization Area<br>w.r.t Injectable main corridor<br>(NLT 12 Pa) |
| 1    | 2-07-2022 13:15:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:16:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:17:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:18:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:19:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:20:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:21:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:22:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:23:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:24:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:25:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:26:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:27:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:28:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:29:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:30:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:31:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:32:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:33:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:34:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:35:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:36:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:37:00 | ****   | ****                                     | ****  | ****  | ****  |
| 1    | 2-07-2022 13:38:00 | ****   | ****                                     | ****  | ****  | ****  |

| ACTIVITY         | NAME | SIGNATURE AND DATE |
|------------------|------|--------------------|
| REVIEWED BY USER |      |                    |
| REVIEWED BY QA   |      |                    |



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|----|---------------------|--|---|---|---|---|
| DD | D-MM-YYYY HH:MM:SS  | Washing and Sterilization Area<br>(NMT 30°C) | Washing and Sterilization Area<br>(NMT 80%) | Washing and Sterilization Area<br>w.r.t Unit Preparation Room<br>(NLT 6 Pa) | Washing and Sterilization Area<br>w.r.t Ampoule Decartoning<br>Room (NLT 12 Pa) | Washing and Sterilization Area<br>w.r.t Injectable main corridor<br>(NLT 12 Pa) |
|    | 12-07-2022 13:39:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:40:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:41:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:42:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:43:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:44:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:45:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:46:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:47:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:48:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:49:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:50:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:51:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:52:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:53:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:54:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:55:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:56:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:57:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:58:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 13:59:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 14:00:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 14:01:00 | ****   | ****  | ****  | ****  | ****  |
|    | 12-07-2022 14:02:00 | ****   | ****  | ****  | ****  | ****  |

| ACTIVITY         | NAME | SIGNATURE AND DATE |
|------------------|------|--------------------|
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|---------------------|---|--|---|---|---|
| DD-MM-YYYY HH:MM:SS | Washing and Sterilization Area (NMT 30°C) | Washing and Sterilization Area (NMT 80%) | Washing and Sterilization Area<br>w.r.t Unit Preparation Room<br>(NLT 6 Pa) | Washing and Sterilization Area<br>w.r.t Ampoule Decartoning<br>Room (NLT 12 Pa) | Washing and Sterilization Area<br>w.r.t Injectable main corridor<br>(NLT 12 Pa) |
| 12-07-2022 14:03:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:04:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:05:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:06:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:07:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:08:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:09:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:10:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:11:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:12:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:13:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:14:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| 12-07-2022 14:15:00 | ****                                      | ****                                     | ****  | ****  | ****  |
| Min Value           | ****                                      | ****                                     | ****  | ****  | ****  |
| Max Value           | ****                                      | ****                                     | ****  | ****  | ****  |

End Of Report: From 12-07-2022 13:15:05 To 12-07-2022 14:15:05

| ACTIVITY         | NAME | SIGNATURE AND DATE |
|------------------|------|--------------------|
| REVIEWED BY USER |      |                    |
| REVIEWED BY QA   |      |                    |