



## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 11:23:00    | 21.5   | 67.1  | 22.4   | 60.8  | 22.7                               | 59.3                              | 18.5                               | 62.6                              | 81  | 94  | 43  | 29   |
| 10-07-2022 11:24:00    | 21.5   | 67.3  | 22.4   | 60.7  | 22.7                               | 59.3                              | 18.5                               | 62.8                              | 78  | 95  | 33  | 29   |
| 10-07-2022 11:25:00    | 21.5   | 67.1  | 22.4   | 60.7  | 22.7                               | 59.2                              | 18.5                               | 62.7                              | 79  | 91  | 40  | 29   |
| 10-07-2022 11:26:00    | 21.5   | 66.8  | 22.4   | 60.8  | 22.7                               | 59.2                              | 18.5                               | 62.7                              | 79  | 94  | 42  | 30   |
| 10-07-2022 11:27:00    | 21.5   | 67.2  | 22.4   | 60.7  | 22.7                               | 59.2                              | 18.5                               | 62.6                              | 80  | 94  | 40  | 29   |
| 10-07-2022 11:28:00    | 21.5   | 67.4  | 22.4   | 60.8  | 22.7                               | 59.2                              | 18.5                               | 62.6                              | 81  | 97  | 41  | 29   |
| 10-07-2022 11:29:00    | 21.5   | 66.8  | 22.4   | 60.8  | 22.7                               | 59.2                              | 18.5                               | 62.6                              | 84  | 95  | 41  | 30   |
| 10-07-2022 11:30:00    | 21.5   | 66.9  | 22.4   | 60.8  | 22.7                               | 59.2                              | 18.5                               | 62.6                              | 76  | 93  | 39  | 30   |
| 10-07-2022 11:31:00    | 21.4   | 67.2  | 22.4   | 60.7  | 22.7                               | 59.2                              | 18.5                               | 62.4                              | 79  | 95  | 41  | 29   |
| 10-07-2022 11:32:00    | 21.4   | 67.1  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.4                               | 62.4                              | 80  | 91  | 42  | 29   |
| 10-07-2022 11:33:00    | 21.5   | 66.9  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.4                               | 62.4                              | 83  | 94  | 40  | 29   |
| 10-07-2022 11:34:00    | 21.4   | 67.3  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.5                               | 62.4                              | 82  | 91  | 41  | 28   |
| 10-07-2022 11:35:00    | 21.4   | 67.1  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.4                               | 62.4                              | 83  | 94  | 40  | 31   |

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



## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 11:36:00    | 21.4   | 66.8  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.5                               | 62.3                              | 82  | 92  | 41  | 29   |
| 10-07-2022 11:37:00    | 21.4   | 67.3  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.5                               | 62.2                              | 80  | 93  | 41  | 30   |
| 10-07-2022 11:38:00    | 21.4   | 67.1  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.5                               | 62.1                              | 84  | 93  | 41  | 29   |
| 10-07-2022 11:39:00    | 21.4   | 66.8  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.6                               | 62                                | 79  | 96  | 41  | 28   |
| 10-07-2022 11:40:00    | 21.5   | 68.2  | 22.4   | 60.6  | 22.7                               | 59.1                              | 18.6                               | 61.9                              | 83  | 100   | 43  | 23   |
| 10-07-2022 11:41:00    | 21.5   | 67.4  | 22.4   | 60.6  | 22.7                               | 59.1                              | 18.6                               | 61.8                              | 82  | 97  | 40  | 29   |
| 10-07-2022 11:42:00    | 21.5   | 66.8  | 22.4   | 60.6  | 22.7                               | 59                                | 18.6                               | 61.8                              | 82  | 93  | 41  | 29   |
| 10-07-2022 11:43:00    | 21.5   | 66.9  | 22.4   | 60.5  | 22.7                               | 59                                | 18.6                               | 61.8                              | 85  | 100   | 43  | 31   |
| 10-07-2022 11:44:00    | 21.5   | 67  | 22.4   | 60.6  | 22.7                               | 58.9                              | 18.6                               | 61.8                              | 79  | 95  | 41  | 28   |
| 10-07-2022 11:45:00    | 21.5   | 66.6  | 22.4   | 60.5  | 22.7                               | 59                                | 18.6                               | 61.8                              | 82  | 94  | 41  | 29   |
| 10-07-2022 11:46:00    | 21.5   | 66.7  | 22.4   | 60.5  | 22.7                               | 58.9                              | 18.6                               | 61.8                              | 82  | 93  | 41  | 29   |
| 10-07-2022 11:47:00    | 21.5   | 66.9  | 22.4   | 60.6  | 22.7                               | 58.9                              | 18.6                               | 61.7                              | 82  | 94  | 41  | 27   |
| 10-07-2022 11:48:00    | 21.4   | 66.6  | 22.4   | 60.6  | 22.7                               | 59                                | 18.6                               | 61.7                              | 80  | 93  | 41  | 28   |

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| REVIEWED BY QA   |      |                    |



## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 11:49:00    | 21.4   | 66.5  | 22.4   | 60.6  | 22.7                               | 59                                | 18.6                               | 61.8                              | 81  | 97  | 39  | 30   |
| 10-07-2022 11:50:00    | 21.4   | 66.8  | 22.3   | 60.7  | 22.7                               | 59                                | 18.6                               | 61.9                              | 80  | 94  | 40  | 28   |
| 10-07-2022 11:51:00    | 21.4   | 66.8  | 22.4   | 60.7  | 22.7                               | 59                                | 18.5                               | 62                                | 80  | 96  | 40  | 28   |
| 10-07-2022 11:52:00    | 21.4   | 66.5  | 22.3   | 60.7  | 22.7                               | 59.1                              | 18.6                               | 62                                | 81  | 95  | 41  | 29   |
| 10-07-2022 11:53:00    | 21.4   | 66.8  | 22.3   | 60.7  | 22.7                               | 59                                | 18.6                               | 62.1                              | 80  | 98  | 40  | 28   |
| 10-07-2022 11:54:00    | 21.4   | 67  | 22.3   | 60.7  | 22.7                               | 59                                | 18.6                               | 62                                | 80  | 97  | 41  | 28   |
| 10-07-2022 11:55:00    | 21.4   | 66.6  | 22.4   | 60.7  | 22.7                               | 59                                | 18.6                               | 61.9                              | 82  | 98  | 40  | 30   |
| 10-07-2022 11:56:00    | 21.4   | 66.8  | 22.3   | 60.8  | 22.7                               | 59                                | 18.6                               | 61.9                              | 82  | 96  | 41  | 29   |
| 10-07-2022 11:57:00    | 21.4   | 67.1  | 22.3   | 60.7  | 22.7                               | 59                                | 18.6                               | 61.8                              | 82  | 95  | 41  | 29   |
| 10-07-2022 11:58:00    | 21.4   | 66.8  | 22.4   | 60.7  | 22.7                               | 59                                | 18.6                               | 61.9                              | 82  | 96  | 40  | 29   |
| 10-07-2022 11:59:00    | 21.4   | 66.7  | 22.4   | 60.7  | 22.7                               | 59.1                              | 18.6                               | 61.8                              | 82  | 94  | 41  | 29   |
| 10-07-2022 12:00:00    | 21.4   | 67.1  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.6                               | 61.8                              | 82  | 94  | 41  | 29   |
| 10-07-2022 12:01:00    | 21.4   | 67.1  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.8                              | 82  | 93  | 41  | 28   |

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| REVIEWED BY QA   |      |                    |



## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 12:02:00    | 21.4   | 66.8  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.8                              | 81  | 93  | 41  | 29   |
| 10-07-2022 12:03:00    | 21.4   | 67  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.9                              | 81  | 96  | 40  | 29   |
| 10-07-2022 12:04:00    | 21.4   | 67.2  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.8                              | 83  | 94  | 41  | 29   |
| 10-07-2022 12:05:00    | 21.4   | 66.8  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.8                              | 81  | 94  | 40  | 29   |
| 10-07-2022 12:06:00    | 21.4   | 67  | 22.3   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.8                              | 81  | 93  | 42  | 27   |
| 10-07-2022 12:07:00    | 21.4   | 67.3  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.8                              | 80  | 94  | 40  | 29   |
| 10-07-2022 12:08:00    | 21.4   | 67  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.8                              | 81  | 94  | 41  | 29   |
| 10-07-2022 12:09:00    | 21.4   | 66.6  | 22.4   | 60.8  | 22.7                               | 59.2                              | 18.7                               | 61.8                              | 82  | 94  | 41  | 29   |
| 10-07-2022 12:10:00    | 21.4   | 66.9  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.8                              | 82  | 97  | 41  | 28   |
| 10-07-2022 12:11:00    | 21.4   | 67.1  | 22.3   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.7                              | 82  | 95  | 41  | 28   |
| 10-07-2022 12:12:00    | 21.4   | 66.8  | 22.3   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.7                              | 81  | 96  | 40  | 29   |
| 10-07-2022 12:13:00    | 21.4   | 66.8  | 22.4   | 60.8  | 22.7                               | 59.1                              | 18.7                               | 61.7                              | 81  | 95  | 41  | 28   |
| 10-07-2022 12:14:00    | 21.4   | 67.2  | 22.3   | 60.9  | 22.7                               | 59.2                              | 18.7                               | 61.7                              | 82  | 95  | 41  | 28   |

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



## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 12:15:00    | 21.4   | 66.9  | 22.3   | 61  | 22.7                               | 59.2                              | 18.7                               | 61.8                              | 79  | 95  | 41  | 29   |
| 10-07-2022 12:16:00    | 21.4   | 66.6  | 22.4   | 61  | 22.7                               | 59.3                              | 18.7                               | 61.8                              | 79  | 95  | 42  | 29   |
| 10-07-2022 12:17:00    | 21.4   | 67.4  | 22.4   | 60.9  | 22.7                               | 59.2                              | 18.7                               | 63                                | 10  | -4  | 1   | 6  |
| 10-07-2022 12:18:00    | 21.4   | 68.7  | 22.4   | 60.9  | 22.7                               | 59.2                              | 18.8                               | 67.1                              | -4  | -7  | -2  | 0  |
| 10-07-2022 12:19:00    | 21.4   | 68.2  | 22.5   | 60.7  | 22.7                               | 59.5                              | 18.9                               | 64.7                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:20:00    | 21.5   | 68  | 22.6   | 60.6  | 22.8                               | 59.5                              | 19                                 | 64.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:21:00    | 21.6   | 67.6  | 22.7   | 60.5  | 22.8                               | 59.6                              | 19.1                               | 64.1                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:22:00    | 21.6   | 67.1  | 22.8   | 60.3  | 22.8                               | 59.6                              | 19.2                               | 64                                | 0   | 0   | 0   | 0  |
| 10-07-2022 12:23:00    | 21.7   | 66.6  | 22.8   | 60.2  | 22.8                               | 59.6                              | 19.2                               | 63.8                              | 0   | -1  | 0   | 0  |
| 10-07-2022 12:24:00    | 21.8   | 66.5  | 22.9   | 60  | 22.8                               | 59.7                              | 19.3                               | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:25:00    | 21.8   | 66.4  | 23   | 59.8  | 22.8                               | 59.6                              | 19.3                               | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:26:00    | 21.8   | 66.2  | 23   | 59.7  | 22.8                               | 59.6                              | 19.4                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:27:00    | 21.8   | 66.1  | 23.1   | 59.6  | 22.8                               | 59.6                              | 19.4                               | 63.6                              | 0   | 0   | 0   | 0  |

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



## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 12:28:00    | 21.8   | 65.9  | 23.2   | 59.5  | 22.9                               | 59.6                              | 19.4                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:29:00    | 21.8   | 65.8  | 23.2   | 59.4  | 22.8                               | 59.6                              | 19.5                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:30:00    | 21.9   | 65.7  | 23.3   | 59.2  | 22.9                               | 59.6                              | 19.5                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:31:00    | 21.9   | 65.6  | 23.3   | 59.1  | 22.9                               | 59.6                              | 19.6                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:32:00    | 21.9   | 65.4  | 23.4   | 59  | 22.9                               | 59.6                              | 19.6                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:33:00    | 21.9   | 65.3  | 23.4   | 58.7  | 22.9                               | 59.6                              | 19.6                               | 63.3                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:34:00    | 21.9   | 65.2  | 23.5   | 58.5  | 22.9                               | 59.6                              | 19.7                               | 63.3                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:35:00    | 21.9   | 65.1  | 23.6   | 58.4  | 22.9                               | 59.6                              | 19.7                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:36:00    | 22   | 65  | 23.7   | 58.2  | 23                                 | 59.6                              | 19.7                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:37:00    | 22   | 64.9  | 23.7   | 58.1  | 23                                 | 59.5                              | 19.8                               | 63.3                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:38:00    | 22   | 64.6  | 23.8   | 57.9  | 23                                 | 59.6                              | 19.8                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:39:00    | 22   | 64.6  | 23.9   | 57.7  | 23                                 | 59.6                              | 19.8                               | 63.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:40:00    | 22.1   | 64.6  | 23.9   | 57.5  | 23                                 | 59.5                              | 19.8                               | 63.5                              | 0   | 0   | 0   | 0  |

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



# SOMERSET THERAPEUTICS LIMITED

## DATA REPORT - SVP1 AND AMPOULE LINE EMS

### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 12:41:00    | 22.1   | 64.5  | 24   | 57.3  | 23                                 | 59.5                              | 19.8                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:42:00    | 22.1   | 64.4  | 24   | 57.3  | 23                                 | 59.5                              | 19.9                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:43:00    | 22.1   | 64.3  | 24.1   | 57.2  | 23                                 | 59.5                              | 19.9                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:44:00    | 22.1   | 64.2  | 24.2   | 57  | 23                                 | 59.5                              | 19.9                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:45:00    | 22.1   | 64.1  | 24.2   | 56.9  | 23.1                               | 59.5                              | 19.9                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:46:00    | 22.1   | 63.9  | 24.2   | 56.8  | 23.1                               | 59.5                              | 20                                 | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:47:00    | 22.2   | 63.8  | 24.2   | 56.8  | 23.1                               | 59.5                              | 20                                 | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:48:00    | 22.2   | 63.8  | 24.2   | 56.7  | 23.1                               | 59.5                              | 20                                 | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:49:00    | 22.2   | 63.8  | 24.3   | 56.6  | 23.1                               | 59.5                              | 20.1                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:50:00    | 22.2   | 63.7  | 24.3   | 56.6  | 23.1                               | 59.5                              | 20.1                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:51:00    | 22.2   | 63.5  | 24.3   | 56.5  | 23.1                               | 59.4                              | 20.1                               | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:52:00    | 22.3   | 63.5  | 24.4   | 56.4  | 23.1                               | 59.4                              | 20.1                               | 63.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:53:00    | 22.3   | 63.2  | 24.4   | 56.3  | 23.1                               | 59.4                              | 20.1                               | 63.6                              | 0   | 0   | 0   | 0  |

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



## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 12:54:00    | 22.3   | 63.1  | 24.4   | 56.3  | 23.2                               | 59.4                              | 20.2                               | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:55:00    | 22.3   | 63.1  | 24.5   | 56  | 23.2                               | 59.4                              | 20.2                               | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:56:00    | 22.3   | 63  | 24.5   | 56  | 23.2                               | 59.4                              | 20.2                               | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:57:00    | 22.4   | 62.9  | 24.5   | 56  | 23.2                               | 59.3                              | 20.2                               | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:58:00    | 22.4   | 62.8  | 24.6   | 55.9  | 23.2                               | 59.4                              | 20.2                               | 63.7                              | 0   | 0   | 0   | 0  |
| 10-07-2022 12:59:00    | 22.4   | 63  | 24.6   | 55.8  | 23.2                               | 59.3                              | 20.3                               | 63.7                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:00:00    | 22.4   | 62.6  | 24.6   | 55.8  | 23.2                               | 59.3                              | 20.3                               | 63.7                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:01:00    | 22.4   | 62.6  | 24.6   | 55.7  | 23.2                               | 59.2                              | 20.3                               | 63.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:02:00    | 22.5   | 62.5  | 24.6   | 55.7  | 23.2                               | 59.3                              | 20.3                               | 63.7                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:03:00    | 22.6   | 62.5  | 24.6   | 55.7  | 23.2                               | 59.2                              | 20.3                               | 63.7                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:04:00    | 22.7   | 62.2  | 24.6   | 55.7  | 23.3                               | 59.3                              | 20.3                               | 64.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:05:00    | 22.7   | 62.2  | 24.7   | 56  | 23.3                               | 59.3                              | 20.4                               | 64.9                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:06:00    | 22.8   | 58.1  | 24.7   | 55.7  | 23.3                               | 59.6                              | 20.4                               | 64.5                              | 0   | 0   | 0   | 0  |

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





## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 13:07:00    | 22.9   | 58  | 24.8   | 55.6  | 23.3                               | 60.1                              | 20.4                               | 64.5                              | -1  | 0   | 0   | 0  |
| 10-07-2022 13:08:00    | 23   | 57.9  | 24.8   | 55.6  | 23.4                               | 59.5                              | 20.4                               | 64.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:09:00    | 23   | 58  | 24.8   | 55.6  | 23.4                               | 59.3                              | 20.4                               | 64.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:10:00    | 23.1   | 58.1  | 24.8   | 55.4  | 23.4                               | 59.5                              | 20.5                               | 64.6                              | -3  | 0   | 0   | 0  |
| 10-07-2022 13:11:00    | 23.1   | 58.1  | 24.9   | 55.3  | 23.4                               | 59.4                              | 20.5                               | 65.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:12:00    | 23.1   | 58.8  | 24.9   | 55.2  | 23.4                               | 59.3                              | 20.5                               | 66                                | 0   | 0   | 0   | 0  |
| 10-07-2022 13:13:00    | 23.1   | 59  | 24.9   | 55.1  | 23.4                               | 59.3                              | 20.5                               | 66.1                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:14:00    | 23.1   | 57.1  | 24.9   | 55.1  | 23.4                               | 59.3                              | 20.6                               | 66.2                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:15:00    | 23.2   | 56.9  | 25   | 54.9  | 23.4                               | 59.3                              | 20.6                               | 66.4                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:16:00    | 23.2   | 56.8  | 24.9   | 55  | 23.4                               | 59.3                              | 20.6                               | 66.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:17:00    | 23.3   | 57.2  | 25   | 55  | 23.4                               | 59.3                              | 20.6                               | 66.5                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:18:00    | 23.3   | 56.4  | 25   | 54.9  | 23.4                               | 59.3                              | 20.7                               | 66.6                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:19:00    | 23.3   | 57.1  | 25   | 54.9  | 23.5                               | 59.3                              | 20.7                               | 66.6                              | 0   | 0   | 0   | 0  |

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



## SOMERSET THERAPEUTICS LIMITED

### DATA REPORT - SVP1 AND AMPOULE LINE EMS

#### STERILE CORRIDOR

| Date Time              | Temperature                                  | RH  | Temperature                                    | RH  | Temperature                        | RH                                | Temperature                        | RH                                | Differential Pressure                               | Differential Pressure   | Differential Pressure                               | Differential Pressure                            |
|------------------------|--|---|--|---|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|---|---|---|--|
| DD-MM-YYYY<br>HH:MM:SS | Injectable sterile corridor (217) (NMT 25°C) | Injectable sterile corridor (217) (NMT 65%) | Ampoule 4 head manual filling (222) (NMT 25°C) | Ampoule 4 head manual filling (222) (NMT 65%) | SVP filtration 02 (223) (NMT 25°C) | SVP filtration 02 (223) (NMT 65%) | SVP filtration 01 (221) (NMT 25°C) | SVP filtration 01 (221) (NMT 65%) | SVP filtration 02 w.r.t Sterile Corridor (NLT 6 Pa) | Ampoule 4 Head Manual Filling w.r.t Sterile Corridor (NLT 6 Pa) | SVP Filtration-01 w.r.t Sterile corridor (NLT 6 Pa) | Sterile Corridor w.r.t Change Room-03 (NLT 6 Pa) |
| 10-07-2022 13:20:00    | 23.3   | 57.2  | 25   | 54.8  | 23.5                               | 59.3                              | 20.7                               | 66.7                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:21:00    | 23.3   | 57.3  | 25.1   | 54.8  | 23.5                               | 59.3                              | 20.7                               | 66.8                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:22:00    | 23.3   | 56.6  | 25.1   | 54.8  | 23.5                               | 59.3                              | 20.7                               | 66.8                              | 0   | 0   | 0   | 0  |
| 10-07-2022 13:23:00    | 23.3   | 56.3  | 25.1   | 54.7  | 23.5                               | 59.3                              | 20.7                               | 66.8                              | 0   | 0   | 0   | 0  |
| Min Value              | 21.4   | 56.3  | 22.3   | 54.7  | 22.7                               | 58.9                              | 18.4                               | 61.7                              | -4  | -7  | -2  | 0  |
| Max Value              | 23.3   | 68.7  | 25.1   | 61  | 23.5                               | 60.1                              | 20.7                               | 67.1                              | 85  | 100   | 43  | 31   |

End Of Report : From 10-07-2022 11:23:22 To 10-07-2022 13:23:22

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