



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-MM-YYYY HH:MM:SS | Washing and Sterilization Area (NMT 30°C) | Washing and Sterilization Area (NMT 80%) | Washing and Sterilization Area w.r.t Unit Preparation Room (NLT 6 Pa) | Washing and Sterilization Area w.r.t Ampoule Decartoning Room (NLT 12 Pa) | Washing and Sterilization Area w.r.t Injectable main corridor (NLT 12 Pa) |

| | | | | | |
|---------------------|------|------|----|----|----|
| 10-07-2022 11:38:00 | 17.5 | 79.1 | 49 | 22 | 45 |
| 10-07-2022 11:39:00 | 17.5 | 79.2 | 49 | 22 | 45 |
| 10-07-2022 11:40:00 | 17.5 | 79.3 | 36 | 19 | 40 |
| 10-07-2022 11:41:00 | 17.6 | 79.4 | 48 | 21 | 45 |
| 10-07-2022 11:42:00 | 17.6 | 79.4 | 48 | 21 | 45 |
| 10-07-2022 11:43:00 | 17.6 | 79.4 | 48 | 20 | 45 |
| 10-07-2022 11:44:00 | 17.6 | 79.4 | 49 | 21 | 46 |
| 10-07-2022 11:45:00 | 17.6 | 79.1 | 47 | 22 | 45 |
| 10-07-2022 11:46:00 | 17.6 | 78.9 | 49 | 21 | 45 |
| 10-07-2022 11:47:00 | 17.6 | 78.8 | 48 | 22 | 46 |
| 10-07-2022 11:48:00 | 17.6 | 78.7 | 19 | 19 | 43 |
| 10-07-2022 11:49:00 | 17.6 | 78.5 | 49 | 21 | 45 |
| 10-07-2022 11:50:00 | 17.6 | 78.4 | 50 | 22 | 45 |
| 10-07-2022 11:51:00 | 17.6 | 78.1 | 49 | 22 | 45 |
| 10-07-2022 11:52:00 | 17.6 | 78 | 50 | 21 | 46 |
| 10-07-2022 11:53:00 | 17.6 | 77.8 | 49 | 21 | 46 |
| 10-07-2022 11:54:00 | 17.6 | 77.8 | 51 | 21 | 46 |
| 10-07-2022 11:55:00 | 17.6 | 77.8 | 48 | 21 | 46 |
| 10-07-2022 11:56:00 | 17.6 | 77.7 | 49 | 21 | 46 |
| 10-07-2022 11:57:00 | 17.6 | 77.7 | 50 | 22 | 45 |
| 10-07-2022 11:58:00 | 17.6 | 77.7 | 49 | 22 | 47 |
| 10-07-2022 11:59:00 | 17.6 | 77.7 | 49 | 22 | 45 |

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



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-MM-YYYY HH:MM:SS | Washing and Sterilization Area (NMT 30°C) | Washing and Sterilization Area (NMT 80%) | Washing and Sterilization Area w.r.t Unit Preparation Room (NLT 6 Pa) | Washing and Sterilization Area w.r.t Ampoule Decartoning Room (NLT 12 Pa) | Washing and Sterilization Area w.r.t Injectable main corridor (NLT 12 Pa) |

| | | | | | |
|---------------------|------|------|----|----|----|
| 10-07-2022 12:00:00 | 17.6 | 77.7 | 49 | 21 | 45 |
| 10-07-2022 12:01:00 | 17.6 | 77.6 | 49 | 21 | 46 |
| 10-07-2022 12:02:00 | 17.6 | 77.6 | 49 | 21 | 46 |
| 10-07-2022 12:03:00 | 17.6 | 77.5 | 48 | 22 | 46 |
| 10-07-2022 12:04:00 | 17.6 | 77.4 | 49 | 21 | 46 |
| 10-07-2022 12:05:00 | 17.6 | 77.6 | 49 | 22 | 46 |
| 10-07-2022 12:06:00 | 17.6 | 77.5 | 49 | 21 | 46 |
| 10-07-2022 12:07:00 | 17.6 | 77.5 | 49 | 22 | 46 |
| 10-07-2022 12:08:00 | 17.6 | 77.5 | 50 | 22 | 47 |
| 10-07-2022 12:09:00 | 17.6 | 77.6 | 49 | 22 | 46 |
| 10-07-2022 12:10:00 | 17.5 | 77.5 | 49 | 22 | 46 |
| 10-07-2022 12:11:00 | 17.5 | 77.5 | 48 | 22 | 46 |
| 10-07-2022 12:12:00 | 17.5 | 77.6 | 50 | 22 | 46 |
| 10-07-2022 12:13:00 | 17.5 | 77.5 | 50 | 23 | 47 |
| 10-07-2022 12:14:00 | 17.5 | 77.6 | 50 | 21 | 46 |
| 10-07-2022 12:15:00 | 17.5 | 77.6 | 49 | 22 | 46 |
| 10-07-2022 12:16:00 | 17.5 | 77.6 | 48 | 21 | 46 |
| 10-07-2022 12:17:00 | 17.5 | 77.6 | 48 | 13 | 23 |
| 10-07-2022 12:18:00 | 17.5 | 77.7 | 50 | 5 | 11 |
| 10-07-2022 12:19:00 | 17.5 | 77.9 | 52 | 0 | 0 |
| 10-07-2022 12:20:00 | 17.5 | 78.1 | 53 | 0 | 0 |
| 10-07-2022 12:21:00 | 17.5 | 78.2 | 51 | 0 | 0 |

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



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-MM-YYYY HH:MM:SS | Washing and Sterilization Area (NMT 30°C) | Washing and Sterilization Area (NMT 80%) | Washing and Sterilization Area w.r.t Unit Preparation Room (NLT 6 Pa) | Washing and Sterilization Area w.r.t Ampoule Decartoning Room (NLT 12 Pa) | Washing and Sterilization Area w.r.t Injectable main corridor (NLT 12 Pa) |

| | | | | | |
|---------------------|------|------|----|---|---|
| 10-07-2022 12:22:00 | 17.5 | 78.3 | 51 | 0 | 0 |
| 10-07-2022 12:23:00 | 17.4 | 78.5 | 50 | 1 | 0 |
| 10-07-2022 12:24:00 | 17.4 | 78.6 | 52 | 0 | 0 |
| 10-07-2022 12:25:00 | 17.4 | 78.7 | 50 | 0 | 0 |
| 10-07-2022 12:26:00 | 17.4 | 78.8 | 52 | 0 | 0 |
| 10-07-2022 12:27:00 | 17.3 | 78.9 | 51 | 0 | 0 |
| 10-07-2022 12:28:00 | 17.3 | 79 | 52 | 0 | 0 |
| 10-07-2022 12:29:00 | 17.4 | 78.8 | 52 | 0 | 0 |
| 10-07-2022 12:30:00 | 17.4 | 78.8 | 52 | 0 | 0 |
| 10-07-2022 12:31:00 | 17.4 | 78.8 | 52 | 0 | 0 |
| 10-07-2022 12:32:00 | 17.4 | 78.8 | 51 | 0 | 0 |
| 10-07-2022 12:33:00 | 17.3 | 78.7 | 50 | 0 | 0 |
| 10-07-2022 12:34:00 | 17.3 | 78.6 | 51 | 1 | 0 |
| 10-07-2022 12:35:00 | 17.3 | 78.7 | 52 | 0 | 0 |
| 10-07-2022 12:36:00 | 17.3 | 78.8 | 51 | 0 | 0 |
| 10-07-2022 12:37:00 | 17.3 | 78.7 | 52 | 0 | 0 |
| 10-07-2022 12:38:00 | 17.3 | 78.7 | 51 | 0 | 0 |
| 10-07-2022 12:39:00 | 17.3 | 78.7 | 50 | 0 | 0 |
| 10-07-2022 12:40:00 | 17.3 | 78.9 | 51 | 1 | 0 |
| 10-07-2022 12:41:00 | 17.4 | 78.9 | 52 | 0 | 0 |
| 10-07-2022 12:42:00 | 17.4 | 79 | 51 | 0 | 0 |
| 10-07-2022 12:43:00 | 17.3 | 79.1 | 52 | 0 | 0 |

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



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-MM-YYYY HH:MM:SS | Washing and Sterilization Area (NMT 30°C) | Washing and Sterilization Area (NMT 80%) | Washing and Sterilization Area w.r.t Unit Preparation Room (NLT 6 Pa) | Washing and Sterilization Area w.r.t Ampoule Decartoning Room (NLT 12 Pa) | Washing and Sterilization Area w.r.t Injectable main corridor (NLT 12 Pa) |

| | | | | | |
|---------------------|------|------|----|---|----|
| 10-07-2022 12:44:00 | 17.3 | 79.2 | 51 | 1 | 0 |
| 10-07-2022 12:45:00 | 17.3 | 79.3 | 52 | 0 | 0 |
| 10-07-2022 12:46:00 | 17.3 | 79.2 | 52 | 0 | 0 |
| 10-07-2022 12:47:00 | 17.3 | 79.3 | 51 | 0 | 0 |
| 10-07-2022 12:48:00 | 17.3 | 79.3 | 51 | 0 | 0 |
| 10-07-2022 12:49:00 | 17.3 | 79.3 | 50 | 0 | 0 |
| 10-07-2022 12:50:00 | 17.4 | 79.2 | 20 | 0 | -1 |
| 10-07-2022 12:51:00 | 17.3 | 79.3 | 51 | 0 | 0 |
| 10-07-2022 12:52:00 | 17.3 | 79.3 | 51 | 0 | 0 |
| 10-07-2022 12:53:00 | 17.4 | 79.1 | 52 | 0 | 0 |
| 10-07-2022 12:54:00 | 17.4 | 79.2 | 51 | 0 | 0 |
| 10-07-2022 12:55:00 | 17.4 | 79.2 | 52 | 0 | 1 |
| 10-07-2022 12:56:00 | 17.4 | 79.6 | 51 | 0 | 0 |
| 10-07-2022 12:57:00 | 17.4 | 80.1 | 52 | 0 | 0 |
| 10-07-2022 12:58:00 | 17.4 | 80.4 | 51 | 0 | 0 |
| 10-07-2022 12:59:00 | 17.4 | 80.5 | 51 | 0 | 0 |
| 10-07-2022 13:00:00 | 17.4 | 80.6 | 51 | 0 | 0 |
| 10-07-2022 13:01:00 | 17.4 | 80.8 | 52 | 0 | 0 |
| 10-07-2022 13:02:00 | 17.4 | 80.8 | 52 | 0 | 0 |
| 10-07-2022 13:03:00 | 17.4 | 81.2 | 51 | 0 | 0 |
| 10-07-2022 13:04:00 | 17.4 | 81.5 | 51 | 0 | 0 |
| 10-07-2022 13:05:00 | 17.4 | 81.8 | 50 | 0 | 0 |

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



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-MM-YYYY HH:MM:SS | Washing and Sterilization Area (NMT 30°C) | Washing and Sterilization Area (NMT 80%) | Washing and Sterilization Area w.r.t Unit Preparation Room (NLT 6 Pa) | Washing and Sterilization Area w.r.t Ampoule Decartoning Room (NLT 12 Pa) | Washing and Sterilization Area w.r.t Injectable main corridor (NLT 12 Pa) |

| | | | | | |
|---------------------|------|------|----|---|---|
| 10-07-2022 13:06:00 | 17.5 | 82 | 50 | 0 | 0 |
| 10-07-2022 13:07:00 | 17.5 | 82 | 52 | 0 | 0 |
| 10-07-2022 13:08:00 | 17.5 | 82 | 52 | 0 | 0 |
| 10-07-2022 13:09:00 | 17.5 | 81.9 | 50 | 0 | 0 |
| 10-07-2022 13:10:00 | 17.6 | 81.7 | 50 | 0 | 0 |
| 10-07-2022 13:11:00 | 17.6 | 81.5 | 51 | 0 | 0 |
| 10-07-2022 13:12:00 | 17.6 | 81.6 | 51 | 0 | 0 |
| 10-07-2022 13:13:00 | 17.6 | 81.7 | 49 | 1 | 0 |
| 10-07-2022 13:14:00 | 17.6 | 81.8 | 51 | 0 | 0 |
| 10-07-2022 13:15:00 | 17.6 | 81.8 | 50 | 0 | 0 |
| 10-07-2022 13:16:00 | 17.7 | 81.8 | 47 | 0 | 0 |
| 10-07-2022 13:17:00 | 17.6 | 81.8 | 50 | 0 | 0 |
| 10-07-2022 13:18:00 | 17.7 | 81.4 | 49 | 0 | 0 |
| 10-07-2022 13:19:00 | 17.6 | 81.1 | 50 | 0 | 0 |
| 10-07-2022 13:20:00 | 17.6 | 81.1 | 51 | 0 | 0 |
| 10-07-2022 13:21:00 | 17.6 | 80.9 | 50 | 0 | 0 |
| 10-07-2022 13:22:00 | 17.6 | 80.7 | 52 | 0 | 0 |
| 10-07-2022 13:23:00 | 17.6 | 80.5 | 51 | 0 | 0 |
| 10-07-2022 13:24:00 | 17.6 | 80.5 | 50 | 0 | 0 |
| 10-07-2022 13:25:00 | 17.6 | 80.3 | 51 | 0 | 0 |
| 10-07-2022 13:26:00 | 17.6 | 80.1 | 50 | 0 | 0 |
| 10-07-2022 13:27:00 | 17.6 | 80.1 | 50 | 0 | 0 |

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



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-MM-YYYY HH:MM:SS | Washing and Sterilization Area (NMT 30°C) | Washing and Sterilization Area (NMT 80%) | Washing and Sterilization Area w.r.t Unit Preparation Room (NLT 6 Pa) | Washing and Sterilization Area w.r.t Ampoule Decartoning Room (NLT 12 Pa) | Washing and Sterilization Area w.r.t Injectable main corridor (NLT 12 Pa) |

| | | | | | |
|---------------------|------|------|----|----|----|
| 10-07-2022 13:28:00 | 17.5 | 80 | 52 | 0 | 0 |
| 10-07-2022 13:29:00 | 17.5 | 79.9 | 49 | 0 | 0 |
| 10-07-2022 13:30:00 | 17.5 | 79.9 | 30 | 0 | 0 |
| 10-07-2022 13:31:00 | 17.6 | 80 | 50 | 0 | 0 |
| 10-07-2022 13:32:00 | 17.6 | 79.9 | 50 | 0 | 0 |
| 10-07-2022 13:33:00 | 17.5 | 80 | 50 | 0 | 0 |
| 10-07-2022 13:34:00 | 17.6 | 79.9 | 50 | 0 | 0 |
| 10-07-2022 13:35:00 | 17.6 | 80 | 50 | 0 | 0 |
| 10-07-2022 13:36:00 | 17.5 | 80 | 51 | 0 | 0 |
| 10-07-2022 13:37:00 | 17.6 | 79.9 | 50 | 1 | 0 |
| 10-07-2022 13:38:00 | 17.6 | 79.8 | 50 | 0 | 0 |
| Min Value | 17.3 | 77.4 | 19 | 0 | -1 |
| Max Value | 17.7 | 82 | 53 | 23 | 47 |

End Of Report : From 10-07-2022 11:38:36 To 10-07-2022 13:38:36

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