| Laboratory   |  | Quality Control Department (Microbiology Laboratory), Torrent Pharmaceuticals Limited, Village-Bhud, Makhnu Majra, Tehsil-Nalagarh, DisttSolan, Baddi, Himachal Pradesh |   |                      |                              |  |  |
|--|--|---|---|----------------------|------------------------------|--|--|
| Accr   | editation Standard   | ISO/IEC 17025: 2005   | ISO/IEC 17025: 2005   |                      |                              |  |  |
| Disc   | pline  | <b>Biological Testing</b>   |   | Issue Date           | 21.07.2015                   |  |  |
| Certificate Number   |  | T-1150  |   | Valid Until          | 20.07.2017                   |  |  |
| Last   | Amended on   | -   |   | Page                 | 1 of 10                      |  |  |
| S. No. Product /<br>Material of Test   |  | Specific Test Performed   | Test Method Specification against which tests are performed |                      | of Testing /<br>of Detection |  |  |
| I.   | DRUGS & PHARMA   | CEUTICALS   |   |                      |                              |  |  |
| 1.   | Pharmaceutical<br>formulation /<br>Valparin XR 500<br>(Sodium valporate) | Total Aerobic microbial count/ Total Aerobic viable count   | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | 10 cfu/g             | to 1000 cfu/g                |  |  |
|  | Tablets  | Total Yeast and moulds count / Total fungal count   |   | 10 cfu/g             | to 100 cfu/g                 |  |  |
|  |  | Test for specific microorgan  | nisms   |                      |                              |  |  |
|  |  | E. coli   |   | Qualitat<br>(Present | ive<br>/Absent)/g            |  |  |
|  |  | Salmonella  |   | Qualitat<br>(Present | ive<br>/Absent)/10 g         |  |  |
|  |  | Staphylococcus aureus   |   | Qualitat<br>(Present | ive<br>/Absent)/g            |  |  |
|  |  | Pseudomonas aeruginosa  |   | Qualitat<br>(Present | ive<br>/Absent)/ g           |  |  |
| 2. Pharmaceutical<br>Formulation /<br>Valparin Chrono<br>500 (Sodium<br>Valporate) Tablets | Formulation /<br>Valparin Chrono   | Total Aerobic microbial count/ Total Aerobic viable count   | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | 10 cfu/g             | to 1000 cfu/g                |  |  |
|  | Valporate) Tablets   | Total Yeast and moulds count / Total fungal count   |   | 10 cfu/g             | to 100 cfu/g                 |  |  |

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| Discipline         |   | <b>Biological Testing</b>   |   | Issue Date           | 21.07.2015                   |
| Certificate Number |   | T-1150  |   | Valid Until          | 20.07.2017                   |
| Last Amended on    |   | -   |   | Page                 | 2 of 10                      |
| S. No              | . Product /<br>Material of Test                                       | Specific Test Performed   | Test Method Specification against which tests are performed |                      | of Testing /<br>of Detection |
|                    | Pharmaceutical  | Test for specific microorgan  | nisms   |                      |                              |
|                    | Formulation /<br>Valparin Chrono<br>500 (Sodium<br>Valporate) Tablets | E. coli   | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | Qualitat<br>(Present | ive<br>/Absent)/g            |
|                    |   | Salmonella  |   | Qualitat<br>(Present | ive<br>/Absent)/10 g         |
|                    |   | Staphylococcus aureus   |   | Qualitat<br>(Present | ive<br>/Absent)/g            |
|                    |   | Pseudomonas aeruginosa  |   | Qualitat<br>(Present | ive<br>/Absent)/ g           |
| 3.                 | Pharmaceutical<br>formulation /<br>Calcigard Retard                   | Total Aerobic microbial count/ Total Aerobic viable count   | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | 10 cfu/g             | to 1000 cfu/g                |
|                    | (Nifedipine) (Tablet)   | Total Yeast and moulds count / Total fungal count   |   | 10 cfu/g             | to 100 cfu/g                 |
|                    |   | Test for specific microorgan  | nisms   |                      |                              |
|                    |   | E. coli   |   | Qualitat<br>(Present | ive<br>/Absent)/g            |
|                    |   | Salmonella  |   | Qualitat<br>(Present | ive<br>/Absent)/10 g         |
|                    |   | Staphylococcus aureus   |   | Qualitat<br>(Present | ive<br>/Absent)/g            |
|                    |   | Pseudomonas aeruginosa  |   | Qualitat<br>(Present | ive<br>/Absent)/ g           |
|                    |   |   |   |                      |                              |

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**Quality Control Department (Microbiology Laboratory), Torrent** Laboratory Pharmaceuticals Limited, Village-Bhud, Makhnu Majra, Tehsil-Nalagarh, Distt.-Solan, Baddi, Himachal Pradesh ISO/IEC 17025: 2005 **Accreditation Standard Discipline Biological Testing Issue Date** 21.07.2015 **Certificate Number** T-1150 **Valid Until** 20.07.2017 Last Amended on **Page** 3 of 10 S. No. Product / **Specific Test Performed Test Method Specification** Range of Testing / **Limits of Detection Material of Test** against which tests are performed 4. Pharmaceutical Total Aerobic microbial GTP No. GTP/IHT/004 10 cfu/g to 1000 cfu/g count/ Total Aerobic viable Issue Date:-01/11/2014 formulation / Karvil (Carvidilol) count **Tablet** Total Yeast and moulds 10 cfu/g to 100 cfu/g count / Total fungal count Test for specific microorganisms E. coli Qualitative (Present/Absent)/g Salmonella Qualitative (Present/Absent)/10 g Staphylococcus aureus Oualitative (Present/Absent)/g Pseudomonas aeruginosa Qualitative (Present/Absent)/ g 5. **Pharmaceutical** Total Aerobic microbial GTP No. GTP/IHT/004 10 cfu/g to 1000 cfu/g count/ Total Aerobic viable Issue Date:-01/11/2014 formulation / Lamotrigine count (Tablets) Total Yeast and moulds 10 cfu/g to 100 cfu/g count / Total fungal count Test for specific microorganisms E.coli **Oualitative** (Present/Absent)/g Salmonella Qualitative (Present/Absent)/10 g

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Quality Control Department (Microbiology Laboratory), Torrent Pharmaceuticals Limited, Village-Bhud, Makhnu Majra, Tehsil-Nalagarh, Laboratory

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**Accreditation Standard** ISO/IEC 17025: 2005

Discipline **Biological Testing** Issue Date 21.07.2015

**Certificate Number** T-1150 Valid Until 20.07.2017

Last Amended on Page 4 of 10

| S. No. | Product /<br>Material of Test                        | Specific Test Performed                                   | Test Method Specification<br>against which tests are<br>performed | Range of Testing /<br>Limits of Detection |
|--------|--|---|---|---|
|        | Pharmaceutical<br>formulation /<br>Lamotrigine       | Staphylococcus aureus                                     | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014                     | Qualitative<br>(Present/Absent)/g         |
|        | (Tablets)  | Pseudomonas aeruginosa                                    |   | Qualitative<br>(Present/Absent)/ g        |
| 6.     | Pharmaceutical<br>formulation /<br>Lisinopril Tablet | Total Aerobic microbial count/ Total Aerobic viable count | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014                     | 10 cfu/g to 1000 cfu/g                    |
|        |  | Total Yeast and moulds count / Total fungal count         |   | 10 cfu/g to 100 cfu/g                     |
|        |  | Test for specific microorgan                              | nisms   |   |
|        |  | E. coli   |   | Qualitative (Present/Absent)/g            |
|        |  | Salmonella  |   | Qualitative (Present/Absent)/10 g         |
|        |  | Staphylococcus aureus                                     |   | Qualitative<br>(Present/Absent)/g         |
|        |  | Pseudomonas aeruginosa                                    |   | Qualitative<br>(Present/Absent)/ g        |
| 7.     | Pharmaceutical formulation / Lamitor                 | Total Aerobic microbial count/ Total Aerobic viable count | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014                     | 10 cfu/g to 1000 cfu/g                    |
|        | (Lamotrigine)<br>(Tablets)                           | Total Yeast and moulds count / Total fungal count         |   | 10 cfu/g to 100 cfu/g                     |

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| Discipline         |   | <b>Biological Testing</b>                                 |  | Issue Date            | 21.07.2015                   |
| Certificate Number |   | T-1150  |  | Valid Until           | 20.07.2017                   |
| Last Amended on    |   | -   |  | Page                  | 5 of 10                      |
| S. No.             | Product / Material of Test                          | Specific Test Performed                                   | Test Method Specification against which tests are performed                |                       | of Testing /<br>of Detection |
|                    | Pharmaceutical formulation /                        | Test for specific microorgan                              | nisms  |                       |                              |
|                    | Lamitor<br>(Lamotrigine)<br>(Tablets)               | E.coli  | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014                              | Qualitat<br>(Present  | ive<br>/Absent)/g            |
|                    | (Tubles)  | Salmonella  |  | Qualitat:<br>(Present | ive<br>/Absent)/10 g         |
|                    |   | Staphylococcus aureus                                     |  | Qualitat<br>(Present  | ive<br>/Absent)/g            |
|                    |   | Pseudomonas aeruginosa                                    |  | Qualitat<br>(Present  | ive<br>/Absent)/ g           |
| 8.                 | Pharmaceutical<br>formulation /<br>Metformin Tablet | Total Aerobic microbial count/ Total Aerobic viable count | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014                              | 10 cfu/g              | to 1000 cfu/g                |
|                    |   | Total Yeast and moulds count / Total fungal count         |  | 10 cfu/g              | to 100 cfu/g                 |
|                    |   | Test for specific microorgan                              | nisms  |                       |                              |
|                    |   | E.coli  |  | Qualitati<br>(Present | ive<br>/Absent)/g            |
|                    |   | Salmonella  |  | Qualitat<br>(Present  | ive<br>/Absent)/10 g         |
|                    |   | Staphylococcus aureus                                     |  | Qualitat<br>(Present  | ive<br>/Absent)/g            |
|                    |   | Pseudomonas aeruginosa                                    |  | Qualitat<br>(Present  | ive<br>/Absent)/ g           |

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**Quality Control Department (Microbiology Laboratory), Torrent** Laboratory Pharmaceuticals Limited, Village-Bhud, Makhnu Majra, Tehsil-Nalagarh, Distt.-Solan, Baddi, Himachal Pradesh ISO/IEC 17025: 2005 **Accreditation Standard Discipline Biological Testing Issue Date** 21.07.2015 **Certificate Number** T-1150 **Valid Until** 20.07.2017 Last Amended on **Page** 6 of 10 S. No. Product / **Specific Test Performed Test Method Specification** Range of Testing / **Limits of Detection Material of Test** against which tests are performed 9. Total Aerobic microbial GTP No. GTP/IHT/004 10 cfu/g to 1000 cfu/g **Pharmaceutical** count/ Total Aerobic viable Issue Date:-01/11/2014 formulation /Zedott Baby(Racecadotril) count Sachet Total Yeast and moulds 10 cfu/g to 100 cfu/g count / Total fungal count Test for specific microorganisms E. coli **Oualitative** (Present/Absent)/g Salmonella **Oualitative** (Present/Absent)/10 g Staphylococcus aureus **Oualitative** (Present/Absent)/g Pseudomonas aeruginosa Qualitative (Present/Absent)/ g 10. **Pharmaceutical** Total Aerobic microbial GTP No. GTP/IHT/004 10 cfu/g to 1000 cfu/g formulation / count/ Total Aerobic viable Issue Date:-01/11/2014 Pravastatin (Tablet) count Total Yeast and moulds 10 cfu/g to 100 cfu/g count / Total fungal count Test for specific microorganisms E.coli **Oualitative** (Present/Absent)/g Salmonella Qualitative (Present/Absent)/10 g

Anand Deep Gupta Convenor

Laboratory

Quality Control Department (Microbiology Laboratory), Torrent Pharmaceuticals Limited, Village-Bhud, Makhnu Majra, Tehsil-Nalagarh,

Distt.-Solan, Baddi, Himachal Pradesh

**Accreditation Standard** ISO/IEC 17025: 2005

Discipline **Biological Testing** Issue Date 21.07.2015

**Certificate Number** T-1150 Valid Until 20.07.2017

Last Amended on Page 7 of 10

| S. No. | Product / Material of Test                                 | Specific Test Performed                                   | Test Method Specification<br>against which tests are<br>performed | Range of Testing /<br>Limits of Detection |
|--------|--|---|---|---|
|        | Pharmaceutical<br>formulation /<br>Pravastatin (Tablet)    | Staphylococcus aureus                                     | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014                     | Qualitative<br>(Present/Absent)/g         |
|        | Travastatiii (Tabiet)                                      | Pseudomonas aeruginosa                                    |   | Qualitative<br>(Present/Absent)/ g        |
| 11.    | Pharmaceutical formulation / Quintor (Ciprofloyagin)       | Total Aerobic microbial count/ Total Aerobic viable count | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014                     | 10 cfu/g to 1000 cfu/g                    |
| 11.    | (Ciprofloxacin)<br>Tablet                                  | Total Yeast and moulds count / Total fungal count         |   | 10 cfu/g to 100 cfu/g                     |
|        |  | Test for specific microorgan                              | nisms   |   |
|        |  | E. coli   |   | Qualitative (Present/Absent)/g            |
|        |  | Salmonella  |   | Qualitative (Present/Absent)/10 g         |
|        |  | Staphylococcus aureus                                     |   | Qualitative<br>(Present/Absent)/g         |
|        |  | Pseudomonas aeruginosa                                    |   | Qualitative<br>(Present/Absent)/ g        |
|        | Pharmaceutical<br>formulation /<br>Risperidone<br>(Tablet) | Total Aerobic microbial count/ Total Aerobic viable count | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014                     | 10 cfu/g to 1000 cfu/g                    |
|        |  | Total Yeast and moulds count / Total fungal count         |   | 10 cfu/g to 100 cfu/g                     |

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|--------------------|---|---|---|----------------------|------------------------------|
| Accre              | editation Standard  | ISO/IEC 17025: 2005   |   |                      |                              |
| Disci              | pline   | <b>Biological Testing</b>   |   | Issue Date           | 21.07.2015                   |
| Certificate Number |   | T-1150  |   | Valid Until          | 20.07.2017                   |
| Last Amended on    |   | -   |   | Page                 | 8 of 10                      |
| S. No.             | Product /<br>Material of Test   | Specific Test Performed   | Test Method Specification against which tests are performed |                      | of Testing /<br>of Detection |
|                    | Pharmaceutical  | Test for specific microorgar  | nisms   |                      |                              |
|                    | formulation / Risperidone (Tablet)                                    | E.coli  | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | Qualitat<br>(Present | ive<br>/Absent)/g            |
|                    | (140.100)   | Salmonella  |   | Qualitat<br>(Present | ive<br>/Absent)/10 g         |
|                    |   | Staphylococcus aureus   |   | Qualitat<br>(Present | ive<br>/Absent)/g            |
|                    |   | Pseudomonas aeruginosa  |   | Qualitat<br>(Present | ive<br>/Absent)/ g           |
| 13.                | Pharmaceutical<br>formulation /<br>Serenata 50<br>(sertralin) tablets | Total Aerobic microbial count/ Total Aerobic viable count   | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | 10 cfu/g             | to 1000 cfu/g                |
|                    |   | Total Yeast and moulds count / Total fungal count   |   | 10 cfu/g             | to 100 cfu/g                 |
|                    |   | Test for specific microorgan  | nisms   | Qualitat<br>(Present | ive<br>/Absent)/g            |
|                    |   | Salmonella  |   | Qualitat<br>(Present | ive<br>/Absent)/10 g         |
|                    |   | Staphylococcus aureus   |   | Qualitat<br>(Present | ive<br>/Absent)/g            |
|                    |   | Pseudomonas aeruginosa  |   | Qualitat<br>(Present | ive<br>/Absent)/ g           |
|                    |   |   |   |                      |                              |

Anand Deep Gupta Convenor

Laboratory

Quality Control Department (Microbiology Laboratory), Torrent
Pharmaceuticals Limited, Village-Bhud, Makhnu Majra, Tehsil-Nalagarh,
Distt.-Solan, Baddi, Himachal Pradesh

Accreditation Standard ISO/IEC 17025: 2005

Discipline Biological Testing Issue Date 21.07.2015

Certificate Number T-1150 Valid Until 20.07.2017

Last Amended on - Page 9 of 10

| S. No. | Product / Material of Test   | Specific Test Performed                                   | Test Method Specification against which tests are performed | Range of Testing /<br>Limits of Detection |
|--------|--|---|---|---|
| 14.    | Pharmaceutical<br>formulation /<br>Tozaar 25<br>(Losartan          | Total Aerobic microbial count/ Total Aerobic viable count | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | 10 cfu/g to 1000 cfu/g                    |
|        | potassium)<br>Tablet   | Total Yeast and moulds count / Total fungal count         |   | 10 cfu/g to 100 cfu/g                     |
|        |  | Test for specific microorgan                              | nisms   |   |
|        |  | E. coli   |   | Qualitative<br>(Present/Absent)/g         |
|        |  | Salmonella  |   | Qualitative<br>(Present/Absent)/10 g      |
|        |  | Staphylococcus aureus                                     |   | Qualitative<br>(Present/Absent)/g         |
|        |  | Pseudomonas aeruginosa                                    |   | Qualitative<br>(Present/Absent)/ g        |
| 15.    | Pharmaceutical formulation / Torlos 25 (Losartan potaggium) Tohlot | Total Aerobic microbial count/ Total Aerobic viable count | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | 10 cfu/g to 1000 cfu/g                    |
|        | potassium) Tablet  | Total Yeast and moulds count / Total fungal count         |   | 10 cfu/g to 100 cfu/g                     |
|        |  | Test for specific microorgan                              | nisms   |   |
|        |  | E. coli   |   | Qualitative (Present/Absent)/g            |

Laboratory Quality Control Department (Microbiology Laboratory), Torrent

Pharmaceuticals Limited, Village-Bhud, Makhnu Majra, Tehsil-Nalagarh,

Distt.-Solan, Baddi, Himachal Pradesh

Accreditation Standard ISO/IEC 17025: 2005

Discipline Biological Testing Issue Date 21.07.2015

Certificate Number T-1150 Valid Until 20.07.2017

Last Amended on - Page 10 of 10

| S. No. | Product /<br>Material of Test                             | Specific Test Performed                                   | Test Method Specification against which tests are performed | Range of Testing /<br>Limits of Detection |  |  |
|--------|---|---|---|---|--|--|
|        | Pharmaceutical<br>formulation /<br>Torlos 25 (Losartan    | Salmonella  | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | Qualitative<br>(Present/Absent)/10 g      |  |  |
|        | potassium) Tablet   | Staphylococcus aureus                                     |   | Qualitative<br>(Present/Absent)/g         |  |  |
|        |   | Pseudomonas aeruginosa                                    |   | Qualitative<br>(Present/Absent)/ g        |  |  |
| 16.    | Pharmaceutical<br>formulation /<br>Omizac<br>(Omeprazole) | Total Aerobic microbial count/ Total Aerobic viable count | GTP No. GTP/IHT/004<br>Issue Date:-01/11/2014               | 10 cfu/g to 1000 cfu/g                    |  |  |
|        | Capsule   | Total Yeast and moulds count / Total fungal count         |   | 10 cfu/g to 100 cfu/g                     |  |  |
|        |   | Test for specific microorganisms                          |   |   |  |  |
|        |   | E.coli  |   | Qualitative<br>(Present/Absent)/g         |  |  |
|        |   | Salmonella  |   | Qualitative<br>(Present/Absent)/10 g      |  |  |
|        |   | Staphylococcus aureus                                     |   | Qualitative<br>(Present/Absent)/g         |  |  |
|        |   | Pseudomonas aeruginosa                                    |   | Qualitative<br>(Present/Absent)/ g        |  |  |

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