

Name: Guangdong Institute for Drug Control

Address: No.2, Jinbuli, Huifu West Road, Yuexiu District, Guangzhou, Guangdong, China

Registration No. CNAS L2000

Accreditation Criteria: ISO/IEC 17025:2017 and relevant requirements of CNAS

Effective Date: 2023-08-03 Expiry Date: 2028-04-19

SCHEDULE 3 ACCREDITED TESTING SCOPE

| №         | Test Object | Item/Parameter |                                | Standard or Method                 | Note | Effective Date |
|-----------|-------------|----------------|--------------------------------|------------------------------------|------|----------------|
|           |             | №              | Item/ Parameter                |                                    |      |                |
| Chemistry |             |                |                                |                                    |      |                |
| 1、 Drug   |             |                |                                |                                    |      |                |
| 1         | Drug        | 1              | Undue Toxicity                 | ChP2020 VolIV 1141                 |      | 2022-04-28     |
|           |             | 2              | Pyrogens                       | ChP2020 VolIV1142                  |      | 2022-04-28     |
|           |             | 3              | Bacterial Endotoxin            | ChP2020 VolIV 1143、 Guidelines9251 |      | 2022-04-28     |
|           |             | 4              | Vasopressor Substances         | ChP2020 VolIV 1144                 |      | 2022-04-28     |
|           |             | 5              | Depressor Substances           | ChP2020 VolIV1145                  |      | 2022-04-28     |
|           |             | 6              | Sensitization tests            | ChP2020 VolIV 1147                 |      | 2022-04-28     |
|           |             | 7              | Biological Assay of Calcitonin | SoIDJX20000036                     |      | 2022-04-28     |



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|    |                         | №  | Item/ Parameter                              |  |   |                          |            |
|    |                         | 8  | Content of unabsorbed Fe from injection site | SoID JX20010153  |   | 2022-04-28               |            |
|    |                         |  |  | ChP2020 Vol II P207 Iron Dextran Injection   |   | 2022-04-28               |            |
|    |                         | 9  | Assay  |  | ChP2020 VolIV1208(Biological Assay of Heparin)                                | Only Clotting time assay | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1209 (Biological Assay of Chorionic Gonadotrophin)               |                          | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1210(Biological Assay of Oxytocin)                               |                          | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1211(Biological Assay of Insulin)                                |                          | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1213(Biological Assay of Protamine Sulfate)                      |                          | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1216(Biological Assay of Follicle Stimulating)                   |                          | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1217(Biological Assay of Luteinising Hormone)                    |                          | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1218(Biological Assay of Calcitonin)                             |                          | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1205(Biological Assay of Vasopressin)                            |                          | 2022-04-28 |
|    |                         |  |  |  | ChP2020 VolIV1212(Test for the Prolongation Effect of Protamine Zinc Insulin) |                          | 2022-04-28 |
|    |                         | 10   | Muscular Irritation                          | SFDA Technical Guidelines for Irritation 、Sensitization and Hemolysis Research of Human Pharmaceuticals (2014) |   | 2022-04-28               |            |
|    |                         | 11   | Skin Irritation test                         | SFDA Technical Guidelines for Irritation 、Sensitization and Hemolysis Research of Human Pharmaceuticals (2014) |   | 2022-04-28               |            |
| 12 | Skin Sensitization test | SFDA Technical Guidelines for Irritation 、Sensitization and Hemolysis Research of Human Pharmaceuticals (2014) |  | 2022-04-28   |   |                          |            |



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|   |             | №              | Item/ Parameter                             |   |      |                |
|   |             | 13             | Sensitization test                          | SFDA Technical Guidelines for Irritation 、 Sensitization and Hemolysis Research of Human Pharmaceuticals (2014) |      | 2022-04-28     |
|   |             | 14             | Intravascular Irritation test               | SFDA Technical Guidelines for Irritation 、 Sensitization and Hemolysis Research of Human Pharmaceuticals (2014) |      | 2022-04-28     |
|   |             | 15             | Hemolysis test                              | SFDA Technical Guidelines for Irritation 、 Sensitization and Hemolysis Research of Human Pharmaceuticals (2014) |      | 2022-04-28     |
|   |             | 16             | Acute toxicity test                         | SFDA Technical Guidelines for Single dose toxicity study of Human Pharmaceuticals (2014)                        |      | 2022-04-28     |
|   |             |                |   | Hong Kong Registration Technical Guidelines for Chinese Traditional Patent Medicine (2004)                      |      | 2022-04-28     |
|   |             | 17             | Long term toxicity test                     | SFDA Technical Guidelines for Repeated dose toxicity study of Human Pharmaceuticals (2014)                      |      | 2022-04-28     |
|   |             |                |   | Hong Kong Registration Technical Guidelines for Chinese Traditional Patent Medicine (2004)                      |      | 2022-04-28     |
|   |             | 18             | Hydroxy-propoxy                             | ChP2020 Vol IV1148  |      | 2022-04-28     |
|   |             | 19             | Mammalian chromosome mutation test in vitro | Technical research guidelines for drug genotoxicity (2018)  |      | 2022-04-28     |
|   |             | 20             | Mammalian micronucleus test in vivo         | Technical research guidelines for drug genotoxicity (2018)  |      | 2022-04-28     |
|   |             | 21             | Step test                                   | Methodology of pharmacological experiment 3rd edition   |      | 2022-04-28     |
|   |             |                |   | Methodology of Pharmacological research in Chinese medicine (1993)  |      | 2022-04-28     |
|   |             | 22             | water maze test                             | Methodology of pharmacological experiment 3rd edition   |      | 2022-04-28     |



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|                       |                     | №              | Item/ Parameter  |  |                              |                |
|                       |                     |                |  | Methodology of Pharmacological research in Chinese medicine (1993) |                              | 2022-04-28     |
|                       |                     | 23             | Identification   | ChP2020 VolIV1001 (PCR)  |                              | 2022-04-28     |
|                       |                     | 24             | Substance of histamine   | ChP2020 VolIV1146  |                              | 2022-04-28     |
|                       |                     | 25             | Substance of estrogen/Estrogenic activity                          | USP-NF (Official Prior to 1-Jul-2018)                              |                              | 2022-04-28     |
|                       |                     |                |  | ChP2020 Vol II 1029  |                              | 2022-04-28     |
| 2、Biological products |                     |                |  |  |                              |                |
| 1                     | Biological products | 1              | Pyrogen  | ChP2020 VolIII1142   |                              | 2022-04-28     |
|                       |                     | 2              | Bacterial Endotoxin  | ChP2020 VolIII1143   |                              | 2022-04-28     |
|                       |                     | 3              | Undue Toxicity   | ChP2020 VolIII1141   |                              | 2022-04-28     |
|                       |                     | 4              | Determination of titer of rabies vaccine for human use             | ChP2020 VolIII3503   | Accredited only for method 1 | 2022-04-28     |
|                       |                     | 5              | Determination of tetanus antitoxin titer (mouse test method)       | ChP 2020Vol III 3508   |                              | 2023-08-03     |
|                       |                     | 6              | Rabies immunoglobulin titer determination method (method 1: mouse) | ChP 2020Vol III 3512   |                              | 2023-08-03     |



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|            |             | №              | Item/ Parameter                                     |  |      |                |
|            |             |                | neutralization test method (arbitration method))    |  |      |                |
| 3、Cosmetic |             |                |   |  |      |                |
| 1          | Cosmetics   | 1              | Acute dermal toxicity test                          | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /3  |      | 2022-04-28     |
|            |             | 2              | Acute oral toxicity test                            | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /2  |      | 2022-04-28     |
|            |             | 3              | Dermal irritation/corrosion test                    | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /4  |      | 2022-04-28     |
|            |             | 4              | Acute eye irritation/corrosion test                 | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /5  |      | 2022-04-28     |
|            |             | 5              | Skin sensitisation test                             | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /6  |      | 2022-04-28     |
|            |             | 6              | Skin phototoxicity test                             | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /7  |      | 2022-04-28     |
|            |             | 7              | Bacterial reverse mutation assay                    | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /8  |      | 2022-04-28     |
|            |             | 8              | In Vitro Mammalian Cells Chromosome Aberration Test | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /9  |      | 2022-04-28     |
|            |             | 9              | In Vitro Mammalian Cells Gene Mutation Test         | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /10 |      | 2022-04-28     |
|            |             | 10             | Mammalian Erythrocyte                               | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /12 |      | 2022-04-28     |



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|                |             | №              | Item/ Parameter   |   |      |                |
|                |             |                | Micronucleus Test   |   |      |                |
|                |             | 11             | Testicle Cells Chromosome Aberration Test                         | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /13                |      | 2022-04-28     |
|                |             | 12             | Skin Sensitization: Local Lymph Node Assay: DA (LLNA:DA)          | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /22                |      | 2022-04-28     |
|                |             | 13             | The Murine Local Lymph Node Assay: BrdU-ELISA                     | 《Safety and Technical Standards for Cosmetics》(2015Edition)Chapter Six Toxicological testing methods /23                |      | 2022-04-28     |
| 4、Health foods |             |                |   |   |      |                |
| 1              | Health food | 1              | Acute oral toxicity test  | National food safety standard Acute oral toxicity test (GB15193.3-2014 )  |      | 2022-04-28     |
|                |             | 2              | Twenty- eight days oral toxicity test                             | TechNational food safety standard Twenty- eight days oral toxicity test (GB 15193.22-2014)                              |      | 2022-04-28     |
|                |             | 3              | Ninety days oral toxicity test                                    | National food safety standard Ninety days oral toxicity test (GB 15193.13-2015)   |      | 2022-04-28     |
|                |             | 4              | Bacterial reverse mutation test                                   | National food safety standard Bacterial reverse mutation test (GB 15193.4-2014)   |      | 2022-04-28     |
|                |             | 5              | Mammalian erythrocyte micronucleus test                           | National food safety standard Mammalian erythrocyte micronucleus test (GB 15193.5-2014)                                 |      | 2022-04-28     |
|                |             | 6              | Chromosome aberration test of Mice spermatogonia or spermatocytes | TechniNational food safety standard Chromosome aberration test of Mice spermatogonia or spermatocytes (GB 15193.8-2014) |      | 2022-04-28     |



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|   |             | №              | Item/ Parameter   |   |                                  |                |
|   |             | 7              | In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test | Technical National food safety standard In Vivo Mammalian Bone Marrow Cell Chromosome Aberration Test (GB 15193.6-2014) |                                  | 2022-04-28     |
|   |             | 8              | teratogenicity study  | National food safety standard Teratogenicity study (GB 15193.14-2015)   |                                  | 2022-04-28     |
|   |             | 9              | Assisting blood lipids reduction function                     | SFDA[2012]107 Appendix 6  | Accredited only for animal tests | 2022-04-28     |
|   |             | 10             | Assisting blood sugar reduction function                      | SFDA[2012]107 Appendix 3  | Accredited only for animal tests | 2022-04-28     |
|   |             | 11             | Antioxidative function  | SFDA[2012]107 Appendix 1  | Accredited only for animal tests | 2022-04-28     |
|   |             | 12             | alleviating lead excretion function                           | SFDA[2012]107 Appendix 7  | Accredited only for animal tests | 2022-04-28     |
|   |             | 13             | Clear the throat function                                     | SFDA[2012]107 Appendix 9  | Accredited only for animal tests | 2022-04-28     |
|   |             | 14             | weight control function                                       | SFDA[2012]107 Appendix 8  | Accredited only for animal tests | 2022-04-28     |
|   |             | 15             | improving nutritional anaemia function                        | SFDA[2012]107 Appendix 5  | Accredited only for animal tests | 2022-04-28     |
|   |             | 16             | Assisting the protection of gastric mucosa function           | SFDA[2012]107 Appendix 2  | Accredited only for animal tests | 2022-04-28     |



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|                           |                 | №              | Item/ Parameter |  |      |                |
| 5、Drug packaging material |                 |                |                 |  |      |                |
| 1                         | Part Parameters | 1              | Undue Toxicity  | Drug packaging material (HDPE Bottles for Oral Solid Preparation) YBB00122002-2015         |      | 2022-04-28     |
| 2                         |                 | 1              | Undue Toxicity  | General Rule for Laminated Films and Pouches for Pharmaceutical Packaging YBB00132002-2015 |      | 2022-04-28     |



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