

Annex

| Category | No. | Items | Description | Fees (NT dollars) |
|---------------------------------------|------------|---|---|------------------------------|
| Common items | A001 | General test | Appearance, average weight, weight variation, disintegration and pH | 2,300 |
| | A002 | Identification | Accounted per compound or method | 3,800 |
| | A003 | Purity test | | 4,900 |
| | A004 | Assay | Accounted per compound or method | 15,100 |
| | A005 | Heavy metal | Accounted per item, analyzed, by means of colorimetry | 3,000 |
| | A006 | Ash | | 1,800 |
| | A007 | Hydrochloride insoluble | | 2,200 |
| | A008 | Control drug and Narcotics | | 3,000 |
| | A009 | Illegal western medicines | | 16,400 |
| | A010 | Nicotine in E-cigarette | | 8,500 |
| | A011 | Unknown compound identification | | 184,000 |
| Drugs, cosmetics, and medical devices | B001 | Dissolution test | | 29,100 |
| | B002 | Content uniformity test | | 28,100 |
| | B003 | Piston syringe (with needle), transfusion apparatus, infusion set, puncture needle, contraceptive devices | Not including sterility test and biological test | 13,500 |
| | B004 | Contact lens | Not including sterility test | 13,400 |
| | B005 | Surgical suture (with needle) | Not including sterility test | 11,500 |
| | B006 | Condom pinholes test | | 7,000 |
| | B007 | Condom bursting test | | 15,800 |
| | B008 | Condom tensile test | | 8,000 |
| | B009 | Condom oven-treated test | | 7,700 |
| | B010 | Surgical masks fluid resistance | | 4,800 |
| | B011 | Surgical mask bacterial filtration efficiency | | 36,000 |
| | B012 | Surgical mask differential pressure test | | 5,000 |
| | B013 | Surgical mask dimensions | | 2,000 |
| | B014 | Surgical mask strap connection point breaking strength test | | 4,600 |
| | B015 | Surgical masks sub-micron particulate filtration efficiency test | | 10,700 |
| | B016 | Surgical masks flammability test | | 5,100 |
| | B017 | Surgical rubber gloves pinholes test | | 13,000 |

Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics

| Category | No. | Items | Description | Fees (NT dollars) |
|----------------------------|------------|---|--|------------------------------|
| | B018 | Infrared ear thermometers accuracy test | | 37,200 |
| | B019 | Electronic sphygmomanometers accuracy test | | 39,800 |
| | B020 | Electronic thermometer accuracy test | | 22,800 |
| Biologics and Drug Biology | C001 | Antibiotic potency test (microbiological method) | | 21,000 |
| | C002 | Chemical test for biologics | | 10,000 |
| | C003 | Sterility test | | 20,000 |
| | C004 | Microbial limit test | | 24,000 |
| | C005 | Thermal stability test for biologics | | 8,000 |
| | C006 | Potency test for biologics | Accounted per compound | 92,000 |
| | C007 | Safety, toxicity, or inactivation test for biologics | Accounted per compound | 50,000 |
| | C008 | PKA level for biologics | | 11,000 |
| | C009 | Written review of test item | Accounted per individual test item | 2,400 |
| | C010 | Moisture for biologics | | 4,600 |
| | C011 | Purity test for biologics | | 6,100 |
| | C012 | Identification for biologics | | 6,500 |
| | C013 | Identification (NAT Method) for biologics | | 22,000 |
| | C014 | Enzyme activity test | Accounted per compound or method | 10,000 |
| | C015 | Diagnostic reagent | | 70,000 |
| | C016 | Diagnostic reagent (NAT Method) | | 90,000 |
| | C017 | Diagnostic reagent (biochip) | | 90,000 |
| | C018 | Bacterial endotoxin test | | 12,000 |
| | C019 | Pyrogen test | | 38,000 |
| | C020 | Biocompatibility test | Accounted per compound or method | 31,000 |
| | C021 | Toxoid preparation or combined toxoid preparation for lot release testing | Potency test fee for biologics charged for each additional type of combined toxoid | 160,000 |
| | C022 | Vaccine preparation or combined vaccine preparation for lot release testing | Potency test fee for biologics charged for each additional type of combined toxoid | 140,000 |
| | C023 | DPT vaccine or DPT combined | Potency test fee for | 320,000 |

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| Category | No. | Items | Description | Fees (NT dollars) |
|-----------------------------|------|---|---|----------------------|
| | | vaccine for lot release testing | biologics charged for each additional type of DPT combined vaccine | |
| | C024 | Antitoxins preparation for lot release testing | | 210,000 |
| | C025 | Anti-serum preparation or polyvalent anti-serum preparation for lot release testing | Potency test fee for biologics charged for each additional anti-serum preparation | 210,000 |
| | C026 | Blood preparation from non-human source for lot release testing | | 130,000 |
| | C027 | Bacteria and toxin preparation for lot release testing | | 140,000 |
| | C028 | Diagnostic bacteria and toxin preparation for lot release testing | | 210,000 |
| | C029 | Fees for biologics based on the evaluation of the documents submitted | | 34,000 |
| | C030 | Lot release certification copy fee | Accounted per copy | 200 |
| | C031 | Human serum (plasma) albumin preparation for lot release testing | | 60,000 |
| | C032 | Human immunoglobulin preparation for lot release testing | | 170,000 |
| | C033 | Hepatitis B immunoglobulin and specific immunoglobulin preparation for Lot Release Testing | | 150,000 |
| | C034 | Clotting factor and clotting compound preparation for lot release testing | | 160,000 |
| | C035 | Fibrin sealant kit for lot release testing | | 170,000 |
| | C036 | Lot release fee for biologics | See appendix | 7,500~ 650,000 |
| Travel Fees for Lot Release | D001 | Area north of Miaoli, including Yilan, but not including the greater Taipei area (Taipei City, New Taipei City, and Keelung City) | Travel fees include sampling and sealing . It should be charged half the price if only sampling or sealing is conducted | 3,400 |
| | D002 | Area from Taichung to Chiayi, including Hualian | Travel fees include sampling and sealing (It should be charged half the price if only sampling or sealing is conducted | 8,200 |
| | D003 | Area south of Tainan, including Taitung | Travel fees include sampling and sealing (It | 10,000 |

| Category | No. | Items | Description | Fees (NT dollars) |
|---|------|---|---|----------------------|
| | | | should be charged half the price if only sampling or sealing is conducted | |
| Chinese herbs, preparations and illegal drugs | E001 | Powder microscopy | | 1,900 |
| | E002 | Cross section microscopy | | 2,600 |
| | E003 | Extract content determination | Accounted per method | 2,300 |
| | E004 | Essential oil determination | | 2,700 |
| | E005 | Chinese herb PCR-DNA sequencing analysis | Accounted per Chinese herb or compound | 11,500 |
| | E006 | Loss on drying | | 2,300 |
| | E007 | Alcohol Determination | | 4,100 |
| | E008 | Ash | | 2,400 |
| | E009 | Acid-Insoluble Ash | | 3,100 |
| | E010 | Drug adulteration | | 24,000 |
| | E011 | Heavy metal | Accounted per item | 12,000 |
| | E012 | (Deleted) | | |
| | E013 | (Deleted) | | |
| | E014 | (Deleted) | | |
| | E015 | (Deleted) | | |
| | E016 | Organochlorines | | 12,800 |
| | E017 | Aflatoxin B1B2G1G2 | | 12,200 |
| | E018 | Microbial limit test | | 24,000 |
| | E019 | Documentary review | Accounted per individual test item | 1,700 |
| | E020 | The identification of crude drug for registration of Chinese medicinal preparations | Accounted per crude drug. The prescription contains 2 to 5 crude drugs is double-charged. The prescription contains 6 to 10 crude drugs is triple-charged. The prescription contains more than 11 crude drugs is quadruple-charged. | 6,000 |
| | E021 | Test of marker components in traditional Chinese medicine | | 16,000 |

Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics

| Category | No. | Items | Description | Fees (NT dollars) |
|----------|------|--|--|----------------------|
| | E022 | Residue of sulfur dioxide | | 4,800 |
| Foods | F001 | pH value | | 1,000 |
| | F002 | Methanol | | 9,200 |
| | F003 | Acid value | | 2,600 |
| | F004 | Iodine value | | 2,600 |
| | F005 | Peroxide value | | 2,400 |
| | F006 | Saponification value | | 2,400 |
| | F007 | Fluorescent whitening agent | | 1,800 |
| | F008 | Migration test | | 1,800 |
| | F009 | Material test | | 3,800 |
| | F010 | Heavy metal | Accounted per item | 12,000 |
| | F011 | (Deleted) | | |
| | F012 | (Deleted) | | |
| | F013 | (Deleted) | | |
| | F014 | (Deleted) | | |
| | F015 | Crude fiber | | 5,400 |
| | F016 | Crude protein | | 4,200 |
| | F017 | Crude fat | | 4,000 |
| | F018 | Moisture | | 1,400 |
| | F019 | 3-monochloro-1,2-propandiol in soy sauce | | 26,000 |
| | F020 | Sulfite | | 4,800 |
| | F021 | Saccharides | Including Sucrose, Lactose, Fructose and Glucose | 13,200 |
| | F022 | Colorants | Including Legal and Illegal Coal Tar Dyes | 6,600 |
| | F023 | Sweeteners | Including Saccharin, Cyclamate and Dulcin | 13,200 |
| | F024 | Preservatives | Including Sorbic acid, Benzoic acid, Dehydroacetic acid, <i>p</i> -Hydroxybenzoate esters, Salicylic acid, Propionic acid and Propionate, Accounted per method | 13,200 |

Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics

| Category | No. | Items | Description | Fees (NT dollars) |
|----------|------|---|-----------------------------|----------------------|
| | F025 | Antioxidants | Including BHA, BHT and TBHQ | 13,200 |
| | F026 | Caffeine | | 10,600 |
| | F027 | Formaldehyde (High-performance liquid chromatography) | | 13,200 |
| | F028 | Boric acid | | 2,800 |
| | F029 | Vitamins | | 13,200 |
| | F030 | Formaldehyde | | 5,600 |
| | F031 | Fatty acid percentage composition | | 13,200 |
| | F032 | Hydrogen peroxide | | 1,000 |
| | F033 | Nitrite | | 7,600 |
| | F034 | Polychlorinated biphenyl (PCB) | | 24,000 |
| | F035 | Volatile basic nitrogen (VBN) | | 4,800 |
| | F036 | Nitrosamines | | 24,000 |
| | F037 | Histamine | | 19,200 |
| | F038 | Organophosphates | | 12,800 |
| | F039 | Organochlorines | | 12,800 |
| | F040 | Carbamates | | 11,400 |
| | F041 | Dithiocarbamates | | 11,000 |
| | F042 | Pyrethroids | | 11,400 |
| | F043 | Other pesticide residues | Accounted per item | 11,400 |
| | F044 | Sulfadruugs | | 12,900 |
| | F045 | Methyl mercury | | 18,600 |
| | F046 | Nitrofurans metabolites | | 22,000 |
| | F047 | Malachite green and leucomalachite green | | 22,000 |
| | F048 | β-Agonists | | 22,000 |
| | F049 | Other veterinary drugs | Accounted per method | 26,200 |
| | F050 | Analysis of component with health care effect | | 70,000 |
| | F051 | Aerobic plate count | | 3,400 |
| | F052 | <i>Escherichia coli</i> | | 3,800 |
| | F053 | Coliform | | 3,300 |
| | F054 | Yeasts and molds count | | 5,600 |
| | F055 | Lactic acid bacteria | | 4,800 |

Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics

| Category | No. | Items | Description | Fees (NT dollars) |
|---------------------|------|---|----------------------|----------------------|
| | F056 | Aflatoxin B1B2G1G2 | | 12,200 |
| | F057 | Aflatoxin M1 | | 12,200 |
| | F058 | Extraneous material | | 4,600 |
| | F059 | <i>Pseudomonas aeruginosa</i> | | 4,700 |
| | F060 | Fecal Streptococci | | 5,800 |
| | F061 | Food borne pathogens | accounted per item | 17,000 |
| | F062 | Test of animal-derived ingredients in foods (animal-derived ingredients adulteration in vegetarian foods) | | 34,900 |
| | F063 | Test of animal-derived ingredients in foods (each species) | | 18,500 |
| | F064 | Test of plant-derived ingredients in foods (each species) | | 18,400 |
| | F065 | Quantitative test of genetically modified (GMO) soybean and maize (each event) | | 40,000 |
| | F066 | Qualitative test of genetically modified (GMO) soybean and maize (each event) | | 25,000 |
| | F067 | Test of genetically modified (GMO) foods for registration | | 500,000 |
| | F068 | Test for C4 plant sugars in honey | | 12,700 |
| | F069 | Test for 16-O-methylcafestol in coffee | | 33,900 |
| | F070 | Inorganic arsenic | | 9,100 |
| | F071 | Test of multiresidue analysis for pesticide | Accounted per method | 32,600 |
| Reference Standards | S201 | Reference plasmid for mammal identification | 50 reactions/vial | 5,000 |
| | S202 | Reference plasmid for poultry identification | 50 reactions/vial | 5,000 |
| | S203 | Reference plasmid for fish identification | 50 reactions/vial | 5,000 |
| | S204 | Reference plasmid for toxic mushroom identification | 50 reactions/vial | 5,000 |
| | S205 | Reference plasmid for green onion, onion, garlic, chinese leek and chinese onion identification | 50 reactions/vial | 5,000 |
| | S206 | Reference plasmid for <i>Cordyceps sinensis</i> identification | 50 reactions/vial | 5,000 |
| | S207 | Reference plasmid for <i>Cordyceps militaris</i> identification | 50 reactions/vial | 5,000 |

| Category | No. | Items | Description | Fees (NT dollars) |
|----------|------|---|--|----------------------|
| | S208 | Reference plasmid for <i>Antrodia cinnamomea</i> identification | 50 reactions/vial | 5,000 |
| | S209 | Reference plasmid for swiftlet identification | 50 reactions/vial | 5,000 |
| | S501 | HBsAg <i>ad</i> national standard | 1mL/bottle | 5,000 |
| | S502 | HBV DNA national standard | 0.5mL/bottle | 7,000 |
| | S503 | HBV DNA working reagent | 1mL/bottle×3 | 7,000 |
| | S504 | HCV RNA national standard | 0.5mL/bottle | 7,000 |
| | S505 | HCV RNA Working Reagent | 1mL/bottle×3 | 7,000 |
| | S506 | Parvovirus B19 DNA national standard | 0.5mL/bottle | 7,000 |
| | S507 | Parvovirus B19 DNA working reagent | 1mL/bottle×3 | 7,000 |
| | S508 | HCV genotype 2 RNA National Standard | 0.5mL/bottle | 7,000 |
| | S509 | HIV RNA National Standard | 0.5mL/bottle | 7,000 |
| | S510 | Biological National Standards | Biological national standards including nucleic acids, antigens, plasmids, or vectors of bacteria/ viruses. | 7,000 |
| | S511 | Biological Reference Materials | Biological reference materials including nucleic acids, antigens, plasmids, or vectors of bacteria/ viruses. | 5,000 |
| | S512 | High risk infectious biological national standards or reference materials | | 9,500 |
| | S601 | Glycyrrhizinic acid reference standard | 30mg/bottle | 7,100 |
| | S602 | Paeoniflorin reference standard | 30mg/bottle | 9,700 |
| | S603 | Baicalin reference standard | 30mg/bottle | 8,100 |
| | S604 | Berberine chloride reference standard | 30mg/bottle | 7,500 |
| | S605 | Puerarin reference standard | 30mg/bottle | 9,800 |
| | S606 | Sennoside A reference standard | 20mg/bottle | 10,200 |
| | S607 | Sennoside B reference standard | 20mg/bottle | 10,000 |

Appendix : Lot Release Fees for Biologics

| # of certificate seal/lot | Lot release fee (NT dollars) | # of certificate seal/lot | Lot release fee (NT dollars) |
|---------------------------|------------------------------|---------------------------|------------------------------|
| ≤2,000 | 7,500 | 156,001~158,000 | 330,000 |
| 2,001~4,000 | 11,500 | 158,001~160,000 | 334,000 |
| 4,001~6,000 | 15,500 | 160,001~162,000 | 339,500 |
| 6,001~8,000 | 19,500 | 162,001~164,000 | 343,500 |
| 8,001~10,000 | 23,500 | 164,001~166,000 | 347,500 |
| 10,001~12,000 | 27,500 | 166,001~168,000 | 351,500 |
| 12,001~14,000 | 31,500 | 168,001~170,000 | 355,500 |
| 14,001~16,000 | 35,500 | 170,001~172,000 | 359,500 |
| 16,001~18,000 | 39,500 | 172,001~174,000 | 363,500 |
| 18,001~20,000 | 43,500 | 174,001~176,000 | 367,500 |
| 20,001~22,000 | 49,000 | 176,001~178,000 | 371,500 |
| 22,001~24,000 | 53,000 | 178,001~180,000 | 375,500 |
| 24,001~26,000 | 57,000 | 180,001~182,000 | 381,000 |
| 26,001~28,000 | 61,000 | 182,001~184,000 | 385,000 |
| 28,001~30,000 | 65,000 | 184,001~186,000 | 389,000 |
| 30,001~32,000 | 69,000 | 186,001~188,000 | 393,000 |
| 32,001~34,000 | 73,000 | 188,001~190,000 | 397,000 |
| 34,001~36,000 | 77,000 | 190,001~192,000 | 401,000 |
| 36,001~38,000 | 81,000 | 192,001~194,000 | 405,000 |
| 38,001~40,000 | 85,000 | 194,001~196,000 | 409,000 |
| 40,001~42,000 | 90,500 | 196,001~198,000 | 413,000 |
| 42,001~44,000 | 94,500 | 198,001~200,000 | 417,000 |
| 44,001~46,000 | 98,500 | 200,001~202,000 | 422,500 |
| 46,001~48,000 | 102,500 | 202,001~204,000 | 426,500 |
| 48,001~50,000 | 106,500 | 204,001~206,000 | 430,500 |
| 50,001~52,000 | 110,500 | 206,001~208,000 | 434,500 |
| 52,001~54,000 | 114,500 | 208,001~210,000 | 438,500 |
| 54,001~56,000 | 118,500 | 210,001~212,000 | 442,500 |
| 56,001~58,000 | 122,500 | 212,001~214,000 | 446,500 |
| 58,001~60,000 | 126,500 | 214,001~216,000 | 450,500 |
| 60,001~62,000 | 132,000 | 216,001~218,000 | 454,500 |
| 62,001~64,000 | 136,000 | 218,001~220,000 | 458,500 |
| 64,001~66,000 | 140,000 | 220,001~222,000 | 464,000 |

Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics

| | | | |
|-------------------|---------|-------------------|---------|
| 66,001 ~ 68,000 | 144,000 | 222,001 ~ 224,000 | 468,000 |
| 68,001 ~ 70,000 | 148,000 | 224,001 ~ 226,000 | 472,000 |
| 70,001 ~ 72,000 | 152,000 | 226,001 ~ 228,000 | 476,000 |
| 72,001 ~ 74,000 | 156,000 | 228,001 ~ 230,000 | 480,000 |
| 74,001 ~ 76,000 | 160,000 | 230,001 ~ 232,000 | 484,000 |
| 76,001 ~ 78,000 | 164,000 | 232,001 ~ 234,000 | 488,000 |
| 78,001 ~ 80,000 | 168,000 | 234,001 ~ 236,000 | 492,000 |
| 80,001 ~ 82,000 | 173,500 | 236,001 ~ 238,000 | 496,000 |
| 82,001 ~ 84,000 | 177,500 | 238,001 ~ 240,000 | 500,000 |
| 84,001 ~ 86,000 | 181,500 | 240,001 ~ 242,000 | 505,500 |
| 86,001 ~ 88,000 | 185,500 | 242,001 ~ 244,000 | 509,500 |
| 88,001 ~ 90,000 | 189,500 | 244,001 ~ 246,000 | 513,500 |
| 90,001 ~ 92,000 | 193,500 | 246,001 ~ 248,000 | 517,500 |
| 92,001 ~ 94,000 | 197,500 | 248,001 ~ 250,000 | 521,500 |
| 94,001 ~ 96,000 | 201,500 | 250,001 ~ 252,000 | 525,500 |
| 96,001 ~ 98,000 | 205,500 | 252,001 ~ 254,000 | 529,500 |
| 98,001 ~ 100,000 | 209,500 | 254,001 ~ 256,000 | 533,500 |
| 100,001 ~ 102,000 | 215,000 | 256,001 ~ 258,000 | 537,500 |
| 102,001 ~ 104,000 | 219,000 | 258,001 ~ 260,000 | 541,500 |
| 104,001 ~ 106,000 | 223,000 | 260,001 ~ 262,000 | 547,000 |
| 106,001 ~ 108,000 | 227,000 | 262,001 ~ 264,000 | 551,000 |
| 108,001 ~ 110,000 | 231,000 | 264,001 ~ 266,000 | 555,000 |
| 110,001 ~ 112,000 | 235,000 | 266,001 ~ 268,000 | 559,000 |
| 112,001 ~ 114,000 | 239,000 | 268,001 ~ 270,000 | 563,000 |
| 114,001 ~ 116,000 | 243,000 | 270,001 ~ 272,000 | 567,000 |
| 116,001 ~ 118,000 | 247,000 | 272,001 ~ 274,000 | 571,000 |
| 118,001 ~ 120,000 | 251,000 | 274,001 ~ 276,000 | 575,000 |
| 120,001 ~ 122,000 | 256,500 | 276,001 ~ 278,000 | 579,000 |
| 122,001 ~ 124,000 | 260,500 | 278,001 ~ 280,000 | 583,000 |
| 124,001 ~ 126,000 | 264,500 | 280,001 ~ 282,000 | 588,500 |
| 126,001 ~ 128,000 | 268,500 | 282,001 ~ 284,000 | 592,500 |
| 128,001 ~ 130,000 | 272,500 | 284,001 ~ 286,000 | 596,500 |
| 130,001 ~ 132,000 | 276,500 | 286,001 ~ 288,000 | 600,500 |
| 132,001 ~ 134,000 | 280,500 | 288,001 ~ 290,000 | 604,500 |
| 134,001 ~ 136,000 | 284,500 | 290,001 ~ 292,000 | 608,500 |

Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics

| | | | |
|-------------------|---------|-------------------|---------|
| 136,001 ~ 138,000 | 288,500 | 292,001 ~ 294,000 | 612,500 |
| 138,001 ~ 140,000 | 292,500 | 294,001 ~ 296,000 | 616,500 |
| 140,001 ~ 142,000 | 298,000 | 296,001 ~ 298,000 | 620,500 |
| 142,001 ~ 144,000 | 302,000 | 298,001 ~ 300,000 | 624,500 |
| 144,001 ~ 146,000 | 306,000 | 300,001 ~ 302,000 | 630,000 |
| 146,001 ~ 148,000 | 310,000 | 302,001 ~ 304,000 | 634,000 |
| 148,001 ~ 150,000 | 314,000 | 304,001 ~ 306,000 | 638,000 |
| 150,001 ~ 152,000 | 318,000 | 306,001 ~ 308,000 | 642,000 |
| 152,001 ~ 154,000 | 322,000 | 308,001 ~ 310,000 | 646,000 |
| 154,001 ~ 156,000 | 326,000 | 310,001 ~ 312,000 | 650,000 |