

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

- Article 1 The standards are established in accordance with Article 58 of the Act Governing Food Safety and Sanitation, the second Paragraph of Article 104-2 of the Pharmaceutical Affairs Act, the second Paragraph of Article 76 of the Medical Devices Act, Article 30 of the Cosmetic Hygiene and Safety Act, and Article 10 of the Charges and Fees Act.
- Article 2 Contents of the standards are laid down in the Appendix.
- Article 3 On grounds for humane or relief purposes, biological preparations in the D numbering section of the Appendix that donated for use by international organizations, countries or pharmaceutical corporations can be exempted from all fees upon approval by the central competent authorities.
- Article 4 The standards come into force on the date of promulgation.

Appendix

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	17,000
	A005	Heavy metal	Accounted as Pb, analyzed by means of colorimetry	3,000
	A006	Ash		1,800
	A007	Hydrochloride insoluble		2,200
	A008	Control drug and Narcotics		4,000
	A009	Illegal western medicines		16,400
	A010	Nicotine in E-cigarette		8,500
	A011	Unknown compound identification		184,000
	A012	Multi-target analysis for drug abuse	Accounted per method (Synthetic Cathinones, Phenethylamines, Cannabinoids)	30,000
Drugs, cosmetics, and medical devices	B001	Dissolution		33,100
	B002	Uniformity of dosage units		32,000
	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		4,600

Category	No.	Items	Description	Fees (NT dollars)
		point breaking strength test		
	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
	B018	Infrared ear thermometers accuracy test		37,200
	B019	Electronic sphygmomanometers accuracy test		39,800
	B020	Electronic thermometer accuracy test		22,800
	B021	Inhalation and exhalation resistance test		10,700
	B022	General medical face mask bacterial filtration efficiency		36,000
	B023	General medical face mask differential pressure test		5,000
	B024	<i>In vitro</i> diagnostic device	Additional charge (C013) if special laboratory is required	100,000
Biologics and Drug Biology	C001	Antibiotic potency test (antibiotics and enzyme)	Non-biological potency test is charged as A004	24,000
	C002	Identification and chemical test (purity) for biologics	1. Accounted per compound or method 2. Excludes identification test using next-generation sequencing, digital PCR, etc.	10,000
	C003	Sterility test		23,000
	C004	Microbiological examination of nonsterile products		27,000
	C005	Identification for biologics (next-generation sequencing)	Calculated by type of nucleic acids (DNA, RNA), an additional charge of 60,000 for each additional type	120,000
	C006	Potency test for biologics	1. Accounted per compound 2. Additional charge (C007) if animal test is required 3. Additional charge	99,000

Category	No.	Items	Description	Fees (NT dollars)
			(C012) if cell laboratory is required 4. Additional charge (C013) if BSL-2 or above laboratory is required	
	C007	Safety test (animal test) and other <i>in vivo</i> tests	1. Accounted per compound 2. Additional charge (C013) if BSL-2 or above laboratory is required	70,000
	C008	Identification for biologics (digital PCR)	Accounted per individual run	100,000
	C009	Documents review of test item	Accounted per individual test item	3,400
	C010	Other chemical test for biologics	Test by chromatographic methods such as HPLC	14,000
	C011	Mass spectrometry analysis for biologics	Accounted per type of protein, an additional charge of 8,000/type	42,000
	C012	Cell-based test	Excluding potency test, additional charge (C013) if BSL-2 or above laboratory is required	50,000
	C013	Infectious biological materials test	Apply when using BSL-2 or above laboratory	58,000
	C014	Bacterial endotoxin test	Additional charge (C012) if cell laboratory is required	15,000
	C015	Pyrogen test	1. Additional charge (C012) if cell laboratory is required 2. Additional charge (C007) if animal test is required	45,000
	C016	Biocompatibility test	Accounted per compound or method	31,000
Lot Release for Biologics	D001	Quadrivalent (or below) vaccine for lot release testing		143,000
	D002	Pentavalent to decavalent vaccine for lot release testing		252,000
	D003	Undecavalent (or above) vaccine for lot release testing		361,000

Category	No.	Items	Description	Fees (NT dollars)
	D004	Two types of pathogens combined vaccine for lot release testing	Two pathogens	252,000
	D005	Three types of pathogens combined vaccine for lot release testing	Three pathogens	351,000
	D006	Four types of pathogens combined vaccine for lot release testing	Four pathogens	450,000
	D007	Five types of pathogens combined vaccine for lot release testing	Five pathogens	549,000
	D008	Six types of pathogens combined vaccine for lot release testing	Six pathogens; for more than six pathogens, an additional charge (C006) per additional pathogen	648,000
	D009	Diagnostic toxins, antitoxins and anti-serum for lot release testing		220,000
	D010	Blood preparation from non-human source for lot release testing		142,700
	D011	Bacteria and toxin for lot release testing		143,700
	D012	Human immunoglobulin, clotting factor, clotting compound and fibrin sealant kit for lot release testing		166,000
	D013	Human serum (plasma) albumin for lot release testing		62,600
	D014	Fees based on the evaluation of the documents submitted		36,600
	D015	Lot release sealing fee	See appendix	10,000~326,000
	D016	Non-routine or emergency handling fee	For off-hours, emergency releases, etc., an additional charge per case	10,000
	D017	Lot release certification copy fee	Accounted per copy	200
	D018	Infectious biological materials test	Apply when using BSL-2 or above laboratory	58,000
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

Category	No.	Items	Description	Fees (NT dollars)
	E008	Ash		2,400
	E009	Acid-Insoluble Ash		3,100
	E010	Drug adulteration		24,000
	E011	Heavy metal	Accounted per item	12,000
	E012	Organochlorines		12,800
	E013	Aflatoxin B1B2G1G2		12,200
	E014	Microbiological examination of nonsterile products		27,000
	E015	Documentary review	Accounted per individual test item	2,400
	E016	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
	E017	Test of marker components in traditional Chinese medicine		16,000
E018	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	Applicable to the test of consumption of potassium permanganate, residues after evaporation, phenol and formaldehyde. Other items are charged as A004.	5,500
	F009	Material test	Accounted per item	16,800
	F010	Heavy metal	Accounted per item	12,000
	F011	Crude fiber		5,400
	F012	Crude protein		4,200

Category	No.	Items	Description	Fees (NT dollars)
	F013	Crude fat		4,000
	F014	Moisture		1,400
	F015	3-monochloro-1,2-propandiol		33,000
	F016	Sulfite		4,800
	F017	Saccharides	Including sucrose, lactose, fructose and glucose	13,200
	F018	Colorants	Including legal and illegal coal tar dyes	6,600
	F019	Sweeteners	Including saccharin, cyclamate, dulcin, etc.	13,200
	F020	Preservatives	Including sorbic acid, benzoic acid, dehydroacetic acid, <i>p</i> -hydroxybenzoate esters, salicylic acid, propionic acid and propionate, etc. Accounted per method	13,200
	F021	Antioxidants	Including BHA, BHT, TBHQ, etc.	13,200
	F022	Caffeine		10,600
	F023	Formaldehyde (High-performance liquid chromatography)		13,200
	F024	Boric acid		2,800
	F025	Formaldehyde		5,600
	F026	Fatty acid percentage composition		13,200
	F027	Hydrogen peroxide		1,000
	F028	Nitrite		7,600
	F029	Volatile basic nitrogen (VBN)		4,800
	F030	Nitrosamines		24,000
	F031	Histamine		19,200
	F032	Dithiocarbamates		11,000
	F033	Other pesticide residues	Accounted per method	11,400
	F034	Sulfa drugs and Quinolone		28,800
	F035	Methyl mercury		18,600
	F036	Nitrofurans metabolites		49,300
	F037	Malachite green, leucomalachite green, crystal violet and leucocrystal violet		27,400
	F038	β-Agonists		52,000

Category	No.	Items	Description	Fees (NT dollars)
	F039	Other veterinary drug residues	Accounted per method	26,200
	F040	Analysis of component with health care effect		70,000
	F041	Aerobic plate count		3,400
	F042	<i>Escherichia coli</i>		3,800
	F043	Coliform		3,300
	F044	Yeasts and molds count		5,600
	F045	Lactic acid bacteria		4,800
	F046	Aflatoxin B1B2G1G2		12,200
	F047	Aflatoxin M1		12,200
	F048	Extraneous material		4,600
	F049	<i>Pseudomonas aeruginosa</i>		4,700
	F050	Fecal Streptococci		5,800
	F051	Foodborne pathogens	Accounted per item	17,000
	F052	Test of animal-derived ingredients in foods (animal-derived ingredients adulteration in vegetarian foods)		34,900
	F053	Test of animal-derived ingredients in foods (each species)		18,500
	F054	Test of plant-derived ingredients in foods (each species)		18,400
	F055	Quantitative test of genetically modified soybean and maize (each event)		40,000
	F056	Qualitative test of genetically modified soybean and maize (each event)		25,000
	F057	Test of genetically modified foods for registration		500,000
	F058	Test for C4 plant sugars in honey		12,700
	F059	Test for 16-O-methylcafestol in coffee		33,900
	F060	Inorganic arsenic		20,000
	F061	Glycidyl fatty acid esters		48,100
	F062	Lactic acid bacteria species identification	Accounted per compound or method	9,000
	F063	Test of multiresidue analysis for pesticide (over 300 items)		32,600

Category	No.	Items	Description	Fees (NT dollars)
	F064	Test of multiresidue analysis for pesticide (100-300 items)		29,000
	F065	Test of multiresidue analysis for pesticide (less than 100 items)		19,600
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
	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	1 mL/bottle	5,000
	S502	Biological national standards	Biological national standards including nucleic acids, antigens, plasmids, or vectors of bacteria/ viruses.	8,100
	S503	Biological reference materials	Biological reference materials including nucleic acids, antigens, plasmids, or vectors of bacteria/ viruses.	5,000
	S504	High risk infectious biological national standards or reference materials		12,000
	S601	Glycyrrhizinic acid reference standard	30 mg/bottle	7,100
S602	Paeoniflorin reference standard	30 mg/bottle	9,700	
S603	Baicalin reference standard	30 mg/bottle	8,100	
S604	Berberine chloride reference	30 mg/bottle	7,500	

Category	No.	Items	Description	Fees (NT dollars)
		standard		
	S605	Puerarin reference standard	30 mg/bottle	9,800
	S606	Sennoside A reference standard	20 mg/bottle	10,200
	S607	Sennoside B reference standard	20 mg/bottle	10,000

Appendix : Lot Release Sealing Fees for Biologics

Number of seals/lot	Sealing fee (NT dollars)	Number of seals/lot	Sealing fee (NT dollars)
≤100	0	160,001~164,000	170,000
101~4,000	10,000	164,001~168,000	174,000
4,001~8,000	14,000	168,001~172,000	178,000
8,001~12,000	18,000	172,001~176,000	182,000
12,001~16,000	22,000	176,001~180,000	186,000
16,001~20,000	26,000	180,001~184,000	190,000
20,001~24,000	30,000	184,001~188,000	194,000
24,001~28,000	34,000	188,001~192,000	198,000
28,001~32,000	38,000	192,001~196,000	202,000
32,001~36,000	42,000	196,001~200,000	206,000
36,001~40,000	46,000	200,001~204,000	210,000
40,001~44,000	50,000	204,001~208,000	214,000
44,001~48,000	54,000	208,001~212,000	218,000
48,001~52,000	58,000	212,001~216,000	222,000
52,001~56,000	62,000	216,001~220,000	226,000
56,001~60,000	66,000	220,001~224,000	230,000
60,001~64,000	70,000	224,001~228,000	234,000
64,001~68,000	74,000	228,001~232,000	238,000
68,001~72,000	78,000	232,001~236,000	242,000
72,001~76,000	82,000	236,001~240,000	246,000
76,001~80,000	86,000	240,001~244,000	250,000
80,001~84,000	90,000	244,001~248,000	254,000
84,001~88,000	94,000	248,001~252,000	258,000
88,001~92,000	98,000	252,001~256,000	262,000
92,001~96,000	102,000	256,001~260,000	266,000
96,001~100,000	106,000	260,001~264,000	270,000
100,001~104,000	110,000	264,001~268,000	274,000
104,001~108,000	114,000	268,001~272,000	278,000
108,001~112,000	118,000	272,001~276,000	282,000
112,001~116,000	122,000	276,001~280,000	286,000
116,001~120,000	126,000	280,001~284,000	290,000
120,001~124,000	130,000	284,001~288,000	294,000
124,001~128,000	134,000	288,001~292,000	298,000

128,001~132,000	138,000	292,001~296,000	302,000
132,001~136,000	142,000	296,001~300,000	306,000
136,001~140,000	146,000	300,001~304,000	310,000
140,001~144,000	150,000	304,001~308,000	314,000
144,001~148,000	154,000	308,001~312,000	318,000
148,001~152,000	158,000	312,001~316,000	322,000
152,001~156,000	162,000	316,001~320,000	326,000
156,001~160,000	166,000		