The laboratory of Bureau of Drug and Narcotic, Department of Medical Sciences has been accepted as an accredited laboratory in the field of drug and narcotic testing for the following scopes.

No.	Type of Sample	Test	Method
1	Non-sterile Pharmaceutical Products	Microbial Limit Tests 1. Total Aerobic Microbial Count 2. Total Combined Yeasts and Molds Count	1. Current USP/NF <61> Microbiological Examination of Non-sterile Products: Microbial Enumeration Tests. 2. Current BP Appendix XVI B. Microbiological Examination of Non-sterile Products 3. Current TP Appendix 10.2 Microbial Limit Tests. 4. Current THP Appendix 10.2 Microbial Limit Tests by Membrane Filtration Technique
2	Narcotics (Tablet and Powder)	3. Quantitative analysis of Methamphetamine HCl	In-house Method SOP 22 02 269 in Connection with: 1. Moffat A.C., Osselton M.D. and Widdop B. Clarke's Analysis of Drugs and Poisons in Pharmaceuticals, Body Fluids and Postmortem Material. 3rd ed., London-Chicago: The Pharmaceutical Press, 2004. 2. United Nations, Recommended Methods for the identification and analysis of Amphetamine Methamphetamine and their ring-substituted analogues in seized materials, New York: United Nations, 2006. by GC-FID Technique.

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Reviewed by Head of Laboratory Accreditation Section..Saovanee Aromsook..(Ms.Saovanee Aromsook)

The laboratory of Bureau of Drug and Narcotic, Department of Medical Sciences has been accepted as an accredited laboratory in the field of drug, medical devices and narcotic testing for the following scopes.

No.	Type of Sample	Test	Method
1	Tablets and Capsules	1. Assay for Active Ingredients	1. Current USP / NF
2	Injection, Solution, Suspension	2. Identification	<621> Chromatography,
3	Cream, Ointment	3. Degradation Product, Related Substances, Chromatographic Purity	<857> Ultraviolet-Visible Spectroscopy, <541> Titrimetry, <197> Spectrophotometric Identification Tests 2. Current BP Appendix IIID. Liquid Chromatography, Appendix III A. Thin-layer Chromatography, Appendix II A. Infrared Spectrophotometry, Appendix II B. Ultraviolet and Visible Absorption Spectrophotometry, Appendix VIII A. Non-aqueous Titration, Appendix VIII B. Amperometric, Potentiometric and Voltametric Titrations, Appendix VIII C. Oxygen-flask Combustion
4 5	Injection, Solution, Suspension Cream, Ointment	4. pH	1. Current USP / NF <791> pH 2. Current BP Appendix VL Determination of pH Values

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No.	Type of Sample	Test	Method
6	Tablets and Capsules	5. Dissolution 6. Disintegration	1. Current USP / NF <711> Dissolution, <701> Disintegration 2. Current BP Appendix XII B. Dissolution, Appendix XIIA. Disintegration
7	Active pharmaceutical ingredient for reference substances production, Active Pharmaceutical Ingredient	7. Identification	1. Current USP / NF <197> Spectrophotometric Identification Tests 2. Current BP Appendix II A. Infrared Spectrophotometry Technique
		8. Melting Range	1. Current USP / NF <741> Melting Range or Temperature 2. Current BP Appendix V A. by Differential Scanning Calorimetry, Melting Point Determination Technique
		9. pH	1. Current USP / NF <791> pH 2. Current BP Appendix V L. Determination of pH values
		10. Specific Optical Rotation	1. Current USP / NF <781> Optical Rotation 2. Current BP Appendix V F. Determination of Optical Rotation and Specific Optical Rotation

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No.	Type of Sample	Test	Method
7 (cont.)	Active pharmaceutical ingredient for reference substances production, Active Pharmaceutical Ingredient	11. Water Content 12. Loss on Drying	1. Current USP / NF <921> Water Determination, <731> Loss on Drying 2. Current BP Appendix IX C. Determination of Water, Appendix IX D. Loss on Drying by Karl Fisher Titration and Oven Technique
		13. Degradation Products, Related Substances, Chromatographic Purity	1. Current USP / NF <621> Chromatography 2. Current BP Appendix III D. Liquid Chromatography Technique

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No.	Type of Sample	Test	Method
7 (cont.)	Active pharmaceutical ingredient for reference substances production, Active Pharmaceutical Ingredient	14. Assay for Active Ingredients (Chemical)	1. Current USP / NF <621> Chromatography, <857> Ultraviolet-Visible Spectroscopy, <541> Titrimetry 2. Current BP Appendix III D. Liquid Chromatography, Appendix III A. Thin-layer Chromatography, Appendix II B. Ultraviolet and Visible Absorption Spectrophotometry, Appendix VIII A. Non-aqueous Titration, Appendix VIII B. Amperometric, Potentiometric and Voltametric Titrations Appendix VIII C. Oxygen-flask Combustion
8	Biopharmaceuticals	15. Identification 16. Impurity 17. Assay	In-house Method SOP 22 02 245 Analytical Technique for Biopharmaceuticals: Chromatography
		18. Identification 19. Impurity	In-house Method SOP 22 02 251 Analytical Technique for Biopharmaceuticals: SDS-PAGE / Western Blot or Dot Blot
		20. Identification	In-house Method SOP 22 02 178 Identification for Hyaluronic acid and Hyaluronate: Carbazole Reaction

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No.	Type of Sample	Test	Method
8 (cont.)	Biopharmaceuticals	21. Potency Assay	In-house Method SOP 22 02 247 Analytical Technique for Biopharmaceuticals: Cell-based Assay (Cell Proliferation and Cytokine Activation / Inhibition)
		22. Potency Assay	In-house Method SOP 22 02 248 Analytical Technique for Biopharmaceuticals: ELISA
		23. Impurity	In-house Method SOP 22 02 246 Analytical Technique for Biopharmaceuticals: Capillary Electrophoresis
		24. Refractive Index	In-house Method SOP 22 02 242 Analytical Technique for Biopharmaceuticals: Refractive Index
		25. Container Content	In-house Method SOP 22 02 228 Container Content for Injections
		26. Chemical Element Determination	In-house Method SOP 22 02 295 Analytical Technique for Biopharmaceuticals: Atomic Absorption Spectroscopy
		27. Water Determination	In-house Method SOP 22 02 252 Analytical Technique for Biopharmaceuticals by Water Determination

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No.	Type of Sample	Test	Method
8 (cont.)	Biopharmaceuticals	28. pH Determination	In-house Method SOP 22 02 185 Analytical Technique for Biopharmaceuticals: pH
9	Traditional Medicine *	29. Identification of Dexamethasone and Prednisolone	In-house Method SOP 22 02 060 by Thin Layer Chromatography (TLC) Technique
10	Injection	30. Bacterial Endotoxins	Current USP / NF <85> by Kinetic Turbidity Method
11	Non-sterile pharmaceutical products	Microbial Limit Test 31. Total Aerobic Microbial Count 32. Total Combined Yeasts and Molds Count	1. Current BP, Appendix XVI B. Microbiological Examination of Non-sterile Products 2. Current USP / NF <61> Microbiological Examination of Non-sterile Products: Microbial Enumeration Tests 3. Current TP, Appendix 10.2 Microbial Limit Tests 4. Current THP, Appendix 10.2 Microbial Limit Tests by Plate Count Technique

The laboratory of Bureau of Drug and Narcotic, Department of Medical Sciences has been accepted as an accredited laboratory in the field of drug, medical devices and narcotic testing for the following scopes.

No.	Type of Sample	Test	Method
11 (cont.)	Non-sterile pharmaceutical products	33. Bile-tolerance Gram-Negative Bacteria (Test for Absence and Quantitative Test) 34. *Escherichia coli* 35. *Salmonella* spp. 36. *Clostridium* spp. 37. *Staphylococcus aureus* 38. *Pseudomonas aeruginosa*	1. Current BP, Appendix XVI B. Microbiological Examination of Non-sterile Products 2. Current USP / NF. Chapter <62> Microbiological Examination of Non-sterile Products: Tests for Specified Microorganisms 3. Current TP, Appendix 10.2 Microbial Limit Tests 4. Current THP, Appendix 10.2 Microbial Limit Tests
		39. Bile-tolerance Gram-Negative Bacteria (Test for Absence and Semi-quantitative Test) 40. *Escherichia coli* (Test for Absence and Semi-Quantitative Test) 41. *Salmonella* spp.	1. Current BP, Appendix XVI F. Microbiological Examination of Herbal Medicinal Products for Oral Use

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No.	Type of Sample	Test	Method
12	Sterile Pharmaceutical Products 12.1 Powder for Injection 12.2 Liquid Injection 12.3 LVP 12.4 Dialysis Solution 12.5 Sterile Ophthalmic Solution 12.6 Sterile Solution for Contact Lens 12.7 Sterile Suspension for Injection 12.8 Sterile Ophthalmic Suspension 12.9 Ophthalmic Ointment and Ophthalmic Gel	42. Sterility Test	1. Current BP Appendix XVI A. Test for Sterility 2. Current USP/NF. <71> Sterility Tests
13	Plastic Pellet Type PVC, PP, and PE for Medical Devices and Plastic Containers for Pharmaceutical Preparation	43. *In vitro* Biological Reactivity Test 44. *In vitro* Cytotoxicity Test	1. Current USP / NF <87> by Elution Test Method 2. ISO 10993-5:2009 by Test on Extract Method

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No.	Type of Sample	Test	Method
14	Plastic Containers for Sterile Pharmaceutical Products	45. Permeability to Microorganisms	TIS 531-2558
15	Medical Devices	46. Bacterial Endotoxins	1. Current USP / NF <85> by Kinetic Turbidity Method 2. BS EN 455-3:2015 3. TIS 531-2558 4. TIS 720-2561 5. TIS 764-2561 6. TIS 1298-2562 7. TIS 1426-2561
		47. *In vitro* Cytotoxicity Test	1. ISO 10993-5:2009 by Test on Extract Method 2. TIS 531-2558 3. TIS 720-2561 4. TIS 764-2561 5. TIS 1298-2562 6. TIS 1394-2561 7. TIS 1426-2561
		48. Hemolysis Test	1. TIS 531-2558 2. TIS 720-2561 3. TIS 764-2561 4. TIS 1298-2562 5. TIS 1426-2561

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No.	Type of Sample	Test	Method
16	Sterile Plastic Containers for Human Blood and Blood Components	49. Permeability to Microorganisms	TIS 1298-2562
17	Plastic Pellets and Medical Devices	50. Intracutaneous Test 51. Intracutaneous (Intradermal) Reactivity Test	1. Current USP / NF <88> Biological Reactivity Test, *In vivo* 2. ISO 10993-23:2021: Tests for Irritation
		52. Implantation Test	Current USP / NF <88> Biological Reactivity Test, *In vivo*
		53. Pyrogen Test	1. Current USP / NF <151> Pyrogen Test 2. Current Ph. Eur. (2.6.8) Pyrogens
		54. Systemic Injection Test 55. Acute Systemic Toxicity Test	1. Current USP / NF <88> Biological Reactivity Test, *In vivo* 2. ISO 10993-11:2017

The laboratory of Bureau of Drug and Narcotic, Department of Medical Sciences has been accepted as an accredited laboratory in the field of drug, medical devices and narcotic testing for the following scopes.

No.	Type of Sample	Test	Method
18	Narcotics (Powder)	56. Identification of Heroin Hydrochloride	In-house Method SOP 22 02 132 in connection with: 1. United Nations, Recommended Methods for Testing Opium, Morphine and Heroin, Division of Narcotic Drugs Vienne, 1998. 2. United Nations, Recommended Methods for Testing Heroin, Division of Narcotic Drugs Vienne, 1986. 3. Moffat A.C., Clarke's Isolation and Identification of Drugs in Pharmaceuticals, Body Fluids and Post-mortem Material. 3rd ed., London: The Pharmaceutical Press, 2004. by Color Test and Thin Layer Chromatography (TLC) Technique

The laboratory of Bureau of Drug and Narcotic, Department of Medical Sciences has been accepted as an accredited laboratory in the field of drug, medical devices and narcotic testing for the following scopes.

No.	Type of Sample	Test	Method
19	Narcotics Tablet and Powder	57. Identification of Amphetamines	In-house Method SOP 22 02 133 in connection with: 1. Moffat A.C., Osselton M.D. and Widdop B. Clarke's Analysis of Drugs and Poisons in Pharmaceuticals, Body Fluids and Post-mortem Material. 3rd ed., London-Chicago: The Pharmaceutical Press, 2004. 2. United Nations, Recommended Methods for the Identification and Analysis of Amphetamine Methamphetamine and Their Ring-substituted Analogues in Seized Materials, New York: United Nations, 2006. 3. The United States Pharmacopoeia. The National Formulary, 21st ed. Rockville: United States Pharmacopoeia Convention, Inc.; 1993. p. 1186. by Color Test and Thin Layer Chromatographic (TLC) Technique.
20	Psychotropic substances (Tablets, Capsules, Powders, Injections)	58. Qualitative Analysis of Benzodiazepines	In-house Method SOP 22 02 113 by Thin Layer Chromatography and Gas Chromatography / Mass Spectrometry Techniques

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No.	Type of Sample	Test	Method
21	Plants	59. Qualitative Analysis of Cannabis in Seized Material	In-house Method SOP 22 02 131 in connection with: 1. Narcotics Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare. Manual for Identification of Abused Drugs. 2nd Edition. Japan, 1998. 2. United Nations. Recommended Methods for Testing Cannabis. Division of Narcotic Drugs. Vienna, 1987. 3. United Nations. Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products (Revised and updated). UNODC Vienna, 2009. 4. Japan International Cooperation Agency. Textbook for the Seminar of Identification and Analysis of Abused Drugs of Indochina Region. Japan, 2002. 5. Ministry of Health and Welfare, Manual for Identification of Abused Drugs. 2 nd ed. March, 1998 by Color Test and Thin Layer Chromatographic (TLC) Technique.

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No.	Type of Sample	Test	Method
22	Cannabis Plants, Cannabis Extracts and Medicinal Cannabis Products	60. Quantitative Analysis of Delta-9-tetrahydrocannabinol (THC) and/or Cannabidiol (CBD) in Canabis Plants, Cnanbis Extracts and Canabis Sublingual Drops	In-house Method SOP 22 02 231 by High-Performance Liquid Chromatography-Spectrophotometry Technique
23	Urine	Screening Test 61. Methamphetamine 62. Morphine 63. Cannabinoids 64. Benzodiazepines 65. Cocaine 66. MDMA Group 67. Ketamine	In-house Method SOP 22 02 141 Immunology by Rapid Test Kit Technique
		68. Qualitative and Quantitative Analysis of Amphetamines Group	In-house Method SOP 22 02 189 by Liquid Chromatography-Mass Spectrometry Technique
		69. Qualitative and Quantitative Analysis of Morphine	In-house Method SOP 22 02 176 by Gas Chromatography-Mass Spectrometry Technique
		70. Qualitative and Quantitative Analysis of Cannabinoids	In-house Method SOP 22 02 191 by Gas Chromatography-Mass Spectrometry Technique

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No.	Type of Sample	Test	Method
23	Urine (cont.)	71. Qualitative and Quantitative Analysis of MDMA Group	In-house Method SOP 22 02 189 by Liquid Chromatography-Mass Spectrometry Technique.
		72. Qualitative of Benzodiazepines Group	In-house Method SOP 22 02 244 by Liquid Chromatography-Triple Quadrupole Mass Spectrometry Technique
		73. Qualitative and Quantitative of Cocaine	In-house Method SOP 22 02 180 by Gas Chromatography-Mass Spectrometry Technique
		74. Qualitative and Quantitative Analysis of Mitragynine	In-house Method SOP 22 02 175 by Gas Chromatography-Mass Spectrometry Technique
		75. Qualitative and Quantitative Analysis of Ketamine	In-house Method SOP 22 02 200 by Gas Chromatography-Mass Spectrometry Technique

*** NOTE**

"Traditional Medicines" means any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals and/or minerals) used in the system of traditional practice. It shall not include any sterile preparation, vaccines, any substance derived from human parts, or any isolated and characterized chemical substances.

Defined by

ASEAN AGREEMENT ON TRADITIONAL MEDICINES: Draft as of 19th TFRF Meeting 21 January 2015 (TFRF: The Task Force on ASEAN Regulatory Framework for Traditional Medicines and Health Supplements)

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