

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

No	Type of sample	Test	Method
1	1. Tablets and Capsules 2. Injection, Solution, Suspension 3. Cream, Ointment	1. Assay for Active Ingredients 2. Identification 3. Degradation Products, Related Substances, Chromatographic Purity	1. Current USP / NF <621>, <857>, <541>, <197>. 2. Current BP <Appendix IIID, III A, II A, II B, VIII A, VIII B, VIII C > Chromatography, Infrared Spectrophotometry, Spectrophotometry and Titration Technique.
2	4. Injection, Solution, Suspension 5. Cream, Ointment	4. pH	1. Current USP/NF <791> 2. Current BP <Appendix VL> pH Determination Technique.
3	6. Tablets and Capsules	5. Dissolution 6. Disintegration	1. Current USP / NF <711>, <701>. 2. Current BP <Appendix XIIB> Dissolution, Spectrophotometry Technique, <Appendix XIIIA> Disintegration.
4	7. Active pharmaceutical ingredient for reference substances production, Active Pharmaceutical Ingredient	7. Identification	1. Current USP / NF <197>. 2. Current BP<Appendix II A> Infrared Spectrophotometry Technique.

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No	Type of sample	Test	Method
4	Active pharmaceutical ingredient for reference substances production, Active Pharmaceutical Ingredient (Cont.)	8. Melting Range	1. Current USP / NF <741>. 2. Current BP<Appendix VA>by Differential Scanning Calorimetry, Melting Point Determination Technique.
		9. pH	1. Current USP / NF <791>. 2. Current BP<Appendix VL>by pH Determination Technique.
		10. Specific Optical Rotation	1. Current USP / NF <781> 2. Current BP<Appendix VF>by Optical Rotation Technique.
		11. Degradation Products, Related Substances, Chromatographic Purity	1. Current USP / NF <621> 2. Current BP<Appendix IIID> by Chromatography Technique.
		12. Water content 13. Loss on drying	1. Current USP / NF <921>, <731> 2. Current BP < Appendix IX C, IX D> by Karl Fisher Titration and Oven Technique.

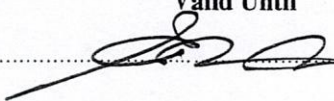
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Reviewed by Head of Laboratory Accreditation Section  (Mr.Surasak Muenphon)

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No	Type of sample	Test	Method
4	Active pharmaceutical ingredient for reference substances production, Active Pharmaceutical Ingredient (Cont.)	14. Assay for Active Ingredients (Chemical)	1. Current USP / NF <621>, <857>, <541>. 2. Current BP <Appendix IIID, III A, II B, VIII A, VIII B, VIII C > Chromatography, Spectrophotometry and Titration Technique.
5	8. Traditional Medicine*	15. Identification of Dexamethasone and Prednisolone	In-house Method SOP 22 02 060 by Thin Layer Chromatography (TLC) Technique.
		Identification of 16. <i>Clostridium</i> spp. 17. <i>Staphylococcus aureus</i> 18. <i>Salmonella</i> spp.	TP Supplement 2005

*** NOTE**

“Traditional Medicines” mean 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, 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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No	Type of sample	Test	Method
6	9. Injection	19. Bacterial Endotoxins	Current USP / NF <85> by Kinetic Turbidity Method.
7	10. Biopharmaceuticals	20. Identification	In-house method SOP 22 02 245 by Chromatography
		21. Impurity	
		22. Assay	
		23. Identification	In-house method SOP 22 02 251 by SDS-PAGE/Western Blot technique
		24. Impurity	
		25. Identification of hyaluronic acid and hyaluronate	In-house method SOP 22 02 178 by Carbazole reaction method
		26. Potency assay - Cell proliferation - Cytokine activation/inhibition	In-house method SOP 22 02 247 by Cell-based assay
		27. Potency assay	In-house method SOP 22 02 248 by ELISA technique
28. Impurity	In-house method SOP 22 02 246 by Capillary electrophoresis technique		
29. Retractive index	In-house method SOP 22 02 242 by Refractometry technique		
30. Container content	In-house method SOP 22 02 228 by volume measuring/weighing technique		

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No	Type of sample	Test	Method
7	Biopharmaceuticals (Cont.)	31. Zinc determination	In-house method SOP 22 02 207 by Atomic Absorption Spectroscopy technique
		32. Water content	In-house method SOP 22 02 252 by Karl-Fisher technique
		33. pH	In-house method SOP 22 02 185 by pH meter
8	11. Non-sterile pharmaceutical products	Microbial Limit Test 34. Total Aerobic Microbial Count 35. Total Combined Yeasts and Moulds 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

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No	Type of sample	Test	Method
8	Non-sterile pharmaceutical products (Cont.)	36. Bile-tolerance Gram Negative Bacteria (Test for Absence and Quantitative Test)	1. Current BP, Appendix XVI B Microbiological Examination of Non-sterile Products. 2. Current USP/NF. <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.
		37. <i>Escherichia coli</i> 38. <i>Salmonella</i> spp. 39. <i>Clostridium</i> spp. 40. <i>Staphylococcus aureus</i> 41. <i>Pseudomonas aeruginosa</i>	
		42. Bile-tolerance Gram Negative Bacteria (Test for absence and Semi-quantitative test) 43. <i>Escherichia coli</i> (Test for absence and Semi-quantitative test) 44. <i>Salmonella</i> spp.	1. Current BP, Appendix XVI F. Microbiological Examination of Herbal Medicinal Products for Oral Use.

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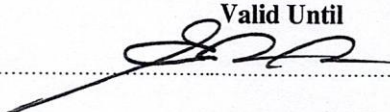
No	Type of sample	Test	Method
9	12. Sterile Pharmaceutical Products - Powder for Injection - Liquid Injection - LVP - Dialysis Solution - Sterile Ophthalmic Solution - Sterile Solution for Contact Lens - Sterile Suspension for Injection - Sterile Ophthalmic Suspension - Ophthalmic Ointment and Ophthalmic Gel	45. Sterility Test	1. Current BP, Appendix XVI A. Test for Sterility. 2. Current USP/NF. <71> Sterility Tests
10	13. Plastic Pellet Type PVC, PP, PE for Medical Devices and Plastic Container for Pharmaceutical Preparation	46. <i>In vitro</i> Biological Reactivity Test 47. <i>In vitro</i> Cytotoxicity Test	1. Current USP / NF <87> by Elution Test Method. 2. ISO 10993-5:2009 by Test on Extract Method
11	14. Plastic Containers for Sterile Pharmaceutical Products	48. Permeability to Microorganisms	TIS 531-2558

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No	Type of sample	Test	Method
12	15. Medical Devices	49. 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
		50. <i>In vitro</i> 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
		51. 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
13	16. Sterile Plastic Containers for Human Blood and Blood Components	52. Permeability to Microorganisms	TIS. 1298-2562
14	17. Plastic Pellet and Medical Devices	53. Intracutaneous Test	1. Current USP/NF <88>
		54. Intracutaneous (Intradermal) Reactivity Test	2. ISO 10993-23:2021
		55. Implantation Test	Current USP/NF <88>
		56. Pyrogen Test	1. Current USP/NF <151> 2. Current Ph. Eur. (2.6.8)
		57. Systemic Injection Test 58. Acute Systemic Toxicity Test	1. Current USP/NF <88> 2. ISO 10993-11:2017



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No	Type of sample	Test	Method
15	18. Narcotics (Powder)	59. Identification of Heroin Hydrochloride	In-house Method SOP 2202132 in Connection with: 1. United Nations, Recommended Methods for Testing Opium, Morphine and Heroin, Division of Narcotic Drugs Vienna, 1998. 2. United Nations, Recommended Method for Testing Heroin, Divisions of Narcotic Drugs Vienna, 1986. 3. Moffat A.C., Clarke's Isolation and Identification of Drugs in Pharmaceuticals, Body Fluids and Post-mortem Material. 3 rd ed., London: The Pharmaceutical Press, 2004. by Color Test and Thin Layer Chromatography Technique.

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No	Type of sample	Test	Method
16	19. Narcotics (Tablet and Powder)	60. Identification of Amphetamines	<p>In-house Method SOP 2202133 in Connection with:</p> <ol style="list-style-type: none"> 1. Moffat A.C., Osselson M.D. and Widdop B., Clark's Analysis of Drugs and Poisons in pharmaceuticals, body fluids and postmortem material. 3 rd 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 State Pharmacopoeia Convention, Inc.; 1993. p. 1186. <p>by Color Test and Thin Layer Chromatography Technique.</p>

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No	Type of sample	Test	Method
17	20. Psychotropic substances (Tablets, Capsules, Powders, Injections)	61. Qualitative Analysis of Benzodiazepines	In-house Method SOP 2202113 by Thin Layer Chromatography and Gas Chromatography/Mass Spectrometry Techniques.
18	21. Plants	62. Qualitative Analysis of Cannabis in Seized Material	In-house Method SOP 2202131 in Connection with: 1. Narcotics Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare. MANUAL FOR IDENTIFICATION OF ABUSED DRUGS.2 nd 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.

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			<p>4. Japan International Cooperation Agency. Textbook for the seminar of Identification and Analysis of Abused Drugs of Indochina Region. Japan, 2002.</p> <p>5. Ministry of Health and Welfare, Manual for Identification of Abused Drugs. 2nd ed. March, 1998.</p> <p>by Color Test and Thin Layer Chromatography Technique.</p>
19	22. Cannabis Plants, Cannabis Extracts and Medicinal Cannabis Products	63. Quantitative Analysis of Delta-9-tetrahydrocannabinol (THC) and/or Cannabidiol (CBD) in Cannabis Plants, Cannabis Extracts and Cannabis Sublingual Drops	In-house Method SOP 2202231 By High Performance Liquid Chromatography - Spectrophotometry Technique.

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No	Type of sample	Test	Method
20	23. Urine	Screening Test 64. Methamphetamine 65. Morphine 66. Cannabinoids 67. Benzodiazepines 68. Cocaine 69. MDMA Group 70. Ketamine	In-house Method SOP 2202141 Immunology by Rapid Test Kit Technique.
		71. Qualitative and Quantitative Analysis of Amphetamines group	In-house Method SOP 2202190 by Gas Chromatography Mass Spectrometry and SOP 2202189 by Liquid Chromatography Mass Spectrometry Technique.
		72. Qualitative and Quantitative Analysis of Morphine	In-house Method SOP 2202176 by Gas Chromatography Mass Spectrometry Technique.
		73. Qualitative and Quantitative Analysis of Cannabinoids	In-house Method SOP 2202191 by Gas Chromatography Mass Spectrometry Technique.
		74. Qualitative and Quantitative Analysis of MDMA group	In-house Method SOP 2202189 by Liquid Chromatography Mass Spectrometry Technique.

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20	Urine (Cont.)	75. Qualitative of Benzodiazepines group	In-house method SOP 22 02 199 by Liquid Chromatography-Triple Quadrupole Mass Spectrometry Technique.
		76. Qualitative and Quantitative of Cocaine	In-house method SOP 22 02 180 by Gas Chromatography Mass Spectrometry Technique.
		77. Qualitative and Quantitative Analysis of Mitragynine	In-house Method SOP 2202175 by Gas Chromatography Mass Spectrometry Technique.
		78. Qualitative and Quantitative Analysis of Ketamine	In-house Method SOP 2202200 by Gas Chromatography Mass Spectrometry Technique.