



Regd. AD | By Hand Delivery

Food & Drugs Administration (Maharashtra State)

Letter No: MH/TZ4/RNW/25-KD/599
 Food & Drugs Administration, KONKAN Division
 OFFICE OF JOINT COMMISSIONER [K.D]
 4TH FL.ESIC BLD,WAGLE ESTATE
 Thane - 400604

License Renewal & Products
 Validity Period:07/03/2016 To 06/03/2021

To :
705119- ANAMOL LABORATORIES PVT.LTD. (Private Limited)
 PLANT 61/12, GENESIS INDUSTRIAL TOWNSHIP (PHASE I/IV) KOLGAON,
 PALGHAR - 401404
 Taluka: Palghar, District: Thane-Zone4

LICENSE No : 25-KD/599
& Dt : 04/11/2016

Sir,

Ref :- Your Inward Application vide Inward ID:- 39487 (RNW) Dated :- 05/03/2016

With reference to your Inward application,we inform you that your said application is considered & following
LICENSE has been **RENEWED**.

Type	Form	LIC No / Validity	First Issue / Rnw
Own: At my OWN Manufacturing Premises	25	KD/599 06/03/2021	07/03/2006 07/03/2016

Prod	Name of Drugs	
1. 531831	Acid Phosphatase	Domestic (IHS(In House))
	- Total ACP (-) - Buffer pH 5.3 (80 mMol/L) - α naphthylphosphate (> 5.0 mMol/L) - Fast Red TR (> 1.0 mMol/L) - NP ACP (-) - Buffer pH 5.3 (80 mMol/L) - α naphthylphosphate (> 5.0 mMol/L) - Fast Red TR (>1.0 mMol/L) - Tartrate (150 mMol/L)	
2. 548007	Albumin	Domestic (IHS(In House))
	- Bromocresol Green (750 μ Mol/L) - Succinate Buffer pH 4.2 (370 μ Mol/L)	
3. 548006	Alkaline Phos.	Domestic (IHS(In House))
	- Diethanolamine Buffer (1 Mol/L) - p-nitrophenyl phosphate (10 mMol/L) - Magnesium Chloride (0.5 mMol/L)	
4. 548021	Amylase	Domestic (IHS(In House))
	- Buffer, pH 6.0 (100 mMol/L) - Gal G2- α CNP (3.0 mMol/L) - Sodium Azide Activators & Stabilizers (152 mMol/L)	
5. 548009	Bilirubin (T & D)	Domestic (IHS(In House))
	- Total BIL (-) - Sulfanilic Acid (32 mMol/L) - Sodium Nitrite (290 μ Mol/L) - Hydrochloric Acid (165 μ Mol/L) - DMSO (7 mMol/L) - Direct BIL (-) - Sulfanilic Acid (32 mMol/L) - Sodium Nitrite (290 μ Mol/L) - Hydrochloric Acid (165 μ Mol/L) - DMSO (-)	
6. 548011	Calcium	Domestic (IHS(In House))
	- Diethanolamine buffer pH 10.7 (500 mMol/L) - O-Cresolphthalein Complexone (63 μ Mol/L) - Quinolinol (17 mMol/L)	
7. 531837	Calcium (Arsenazo III)	Domestic (IHS(In House))
	- Imidazole Buffer pH 7.0 (100 mMol/L) - Arsenazo III (100 μ Mol/L) - 8-Hydroxyquinoline Activators & Stabilizers (5 mM/L)	
8.	CHLORIDE	Domestic (IHS(In House))

Fee Payment(s) : DB-Id: 135450 - 05/03/2016 (Amt: 31500) Balance : 0

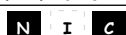
No. of Products: 38 , No. of Ingredients: 221

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Division	MFG ID No	Type:License Renewal	License No	Issue Date
KONKAN (TZ4)	705119	RNW-39487-05/03/2016	25-KD/599	04/11/2016

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531825		- Mercuric Thiocyanate (2.0 mMol/L) - Mercuric Chloride (0.8 mMol/L) - Ferric Nitrate (20.0 mMol/L) - Nitric Acid (45.0 mMol/L)	
9. 548012	Cholesterol	- Goods Buffer ; pH 7.7 (100 mMol/L) - Cholesterol Oxidase (10 IU/L) - Cholesterol esterase (135 IU/L) - Peroxidase (495 IU/L) - 4 Amino antipyrine (0.5 mMol/L) - Phenol (10 mMol/L)	Domestic (IHS(In House))
10. 531828	Creatine Kinase - MB	- Imidazole buffer pH 6.7 (100 mMol/L) - Phosphocreatine (30 mMol/L) - Glucose (20 mMol/L) - N-acetylcystine (10 mMol/L) - Magnesium acetate (10 mMol/L) - EDTA (2 mMol/L) - ADP* (2 mMol/L) - NADP* (2 mMol/L) - AMP* (5 mMol/L) - Adenosine (5') Penta-Phospho (5') - adenosine (AP5A) (10 µMol/L) - Glucose -6- phosphate dehydrogenase (≥ 1.5 kU/L) - Hexokinase (≥ 2.5 kU/L) - CK - M inhibiting polyclonal antibodies inhibiting capacity (≥ 2000 U/L)	Domestic (IHS(In House))
11. 531827	Creatine Kinase - NAC	- Imidazole buffer pH 6.7 (100 mMol/L) - Phosphocreatine (30 mMol/L) - Glucose (20 mMol/L) - N-acetylcystine (20 mMol/L) - Magnesium acetate (10 mMol/L) - EDTA (2 mMol/L) - ADP* (2 mMol/L) - NADP* (2 mMol/L) - AMP* (2 mMol/L) - Adenosine (5') Penta - Phospho (5') - adenosine (AP5A) (10 µMol/L) - Glucose-6-phosphate dehydrogenase (≥ 1.5 kU/L) - Hexokinase (≥ 2.5 kU/L)	Domestic (IHS(In House))
12. 548013	Creatinine	- Sod. Picrate (7.7 mMol/L) - Sod. Hydroxide (500 mMol/L)	Domestic (IHS(In House))
13. 531862	Creatinine (Enzymatic)	- R1 (-) - Buffer pH 7.4 (50 mmol/l) - Creatinine amidohydrolase (21 KU/L) - Sarcosine oxidase (5 KU/L) - Ascorbate oxidase (4.5 KU/L) - ESPMT (0.2 gm/L) - R2 (-) - Buffer pH 7.3 (50 mmol/l) - Creatinine amidohydrolase (250 KU/L) - Peroxidase (8 KU/L) - 4-amino antipyrine (0.5 gm/L)	Domestic (IHS(In House))
14. 548022	Gamma GT	- R1 (-) - Glycylglycine; pH 8.5 (200 mMol/L) - Stabilizers, excipients & Surface active agents (-) - R2 (-) - MES buffer; pH 5.5 (20 mMol/L) - L-y-glutamyl-3-carboxy-4-nitroanilide (≥25 mMol/L) - Stabilizers, excipients & Surface active agents (-)	Domestic (IHS(In House))
15. 548014	Glucose	- Phosphate buffer ; pH 7.7 (170 mMol/L) - Glucose Oxidase (5000 IU/L) - Peroxidase (3000 IU/L) - 4-aminoantipyrine (0.28 mMol/L) - Phenol (16 mMol/L)	Domestic (IHS(In House))
16.	HDL - CHOLESTEROL DIRECT		Domestic (IHS(In House))

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548029		<ul style="list-style-type: none"> - R1 (-) - MOPS buffer (pH 7.0) (Goods buffer) (100 mmol/l) - HDAOS (0.56 mmol/l) - Cholesterol Esterase (800 U/L) - Cholesterol Oxidase (507 U/L) - Catalase (800 U/L) - R2 (-) - MOPS buffer (pH 7.0) (1000 mmol/l) - 4-Aminoantipyrine (4.00 mmol/l) - Peroxidase (4 KU/L) - Sodium Azide (0.01 %) 	
17. 531824	HDL Precipitant	<ul style="list-style-type: none"> - Phosphotungstic Acid (2.4 mMol/L) - Magnesium Chloride (40 mMol/L) 	Domestic (IHS(In House))
18. 531844	IRON	<ul style="list-style-type: none"> - R1 (-) - Acetate buffer pH - 4.9 (170 mmol/l) - Guanidine hydrochloride (04 M) - Hydroxylamine (255 mmol/l) - Thiourea (80 mmol/l) - R2 (-) - Sodium Acetate (170 mmol/l) - Ferrozine (42 mmol/l) 	Domestic (IHS(In House))
19. 548023	LDH	<ul style="list-style-type: none"> - R1 (-) - Tris buffer, (pH 7.5) (100 mMol/L) - Pyruvate (\geq 1.2 mmol/l) - Stabilizers, excipients & Surface active agents (-) - R2 (-) - Tris buffer, (pH 9.5) (20 mmol/l) - NADH (\geq 1.1 mmol/l) - Stabilizers, excipients & Surface active agents (-) 	Domestic (IHS(In House))
20. 548030	LDL - CHOLESTEROL	<ul style="list-style-type: none"> - R1 (-) - PIPES buffer (pH) (Goods Buffer) (50 mmol/l) - N-Ethyl N-(2-hydroxy 3-sulfopropyl)3-methylaniline (2.0 mmol/l) - Cholesterol Esterase (600 U/L) - Cholesterol Oxidase (500 KU/L) - Catalase (600 KU/L) - R2 (-) - PIPES Buffer (pH 7.0) (50 mmol/l) - 4-Aminoantipyrine (4 mMol/L) - Peroxidase (4 KU/L) - Sodium Azide (0.01 %) 	Domestic (IHS(In House))
21. 548031	Lipase	<ul style="list-style-type: none"> - Triolein (0.30 mmol/l) - Tris -buffer (pH 9.2) (26 mmol/l) - Sodium desoxycholate (19 mmol/l) - Calcium Chloride (0.01 mmol/l) - Colipase (3 mmol/l) 	Domestic (IHS(In House))
22. 548024	Magnesium	<ul style="list-style-type: none"> - Tris buffer, (pH 11.0) (200 mmol/l) - GEDTA (60 μmol/l) - Xylidyl blue (110 mmol/l) - Stabilizers, excipients & Surface active agents (-) 	Domestic (IHS(In House))
23. 510397	MALARIA - DETECTION OF MALARIA ANTIGEN / RAPID IMMUNOCHROMATOGRAPHIC TEST FOR QUALITATIVE DETECTION OF MALARIA ANTIGEN FROM BLOOD SAMPLE NITROCELLULOSE MEMBRANE:	<ul style="list-style-type: none"> - MEMBRANE TEST ASSEMBLY COMPRISING OF (-) - TEST REGION : ANTI MALARIA ANTIBODY (-) - CONTROL REGION : ANTI MOUSE ANTIBODY (-) - CONJUGATE PAD : COLLOIDAL GOLD CONJUGATED TO ANTIBODIES SPECIFIC FOR MALARIA ANTIGEN (-) - TEST ASSEMBLY IS HOUSED IN A PLASTIC DEVICE (-) - SAMPLE EXTRACTION BUFFER (-) 	Domestic (IHS(In House))
24. 531134	MALARIA TEST (Plasmodium Detection) / One Kit Components	<ul style="list-style-type: none"> - Acridine Orange (0.12 Gm/L) - Stain Solution Diluent (R2) (-) - Nacl (7.98 gm/L) - Stain Solution (R1) (-) - Tris (2.54 gm/L) - EDTA (pH 8) (780 mg/L) - Disposable Cartridges (-) 	Domestic (IHS(In House))

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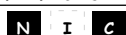
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25. 548020	Phosphorus	- Ammonium molybdate (0.3 mMol/L) - Sulphuric Acid (1.0 %)	Domestic (IHS(In House))
26. 548015	SGOT	- Tris buffer (20 (pH 7.7) mM) - L-Aspartate (200 mM) - NADH (0.15 mM) - LDH * (≥ 200 IU) - α - Ketoglurate (12 mM)	Domestic (IHS(In House))
27. 548016	SGPT	- Tris buffer (pH 7.4) (20 mM) - L-Alanine (200 mM) - NADH (0.15 mM) - LDH * (≥ 2000 IU) - α -Ketoglurate (12 mM)	Domestic (IHS(In House))
28. 510398	SYPHYLIS - DETECTION OF SYPHYLIS ANTIBODY / RAPID IMMUNOCHROMATOGRAPHIC TEST FOR QUALITATIVE DETECTION OF SYPHYLIS ANTIBODY FROM BLOOD SAMPLE NITROCELLULOSE MEMBRANE:	- MEMBRANE TEST ASSEMBLY COMPRISING OF (-) - CONJUGATE PAD : SYPHILIS ANTIGEN COATED PARTICLE AND SYPHILIS ANTIGEN COATED ON MEMBRANE (-) - CONTROL REGION : ANTI MOUSE ANTIBODY. (-) - TEST ASSEMBLY IS HOUSED IN A PLASTIC DEVICE (-) - TEST REGION : RECOMBINANT SYPHILIS ANTIGEN (-) - SAMPLE EXTRACTION BUFFER (-)	Domestic (IHS(In House))
29. 548028	Test Strip For Urine Glucose	- Glucose (-) - Glucose Oxidase (450 units) - Peroxidase (185 units) - Potassium Iodide (10.00 mg)	Domestic (IHS(In House))
30. 548027	Test Strip For Urine Glucose & Kotonas	- Ketones (-) - Sodium Nitroprusside (116 µg)	Domestic (IHS(In House))
31. 548026	Test strip for Urine Glucose & Protein	- Protein Per Strip (-) - Tetrabrommophenol blue (0.30 mg) - Citric Acid (110.00 mg) - Trisodium Citrate (46.00 mg)	Domestic (IHS(In House))
32. 531863	The 3 Test Reagent Strip for Urine, Glucose Protein & pH	- pH (-) - Methyl red (0.04 mg) - Bromothymol blue (0.50 mg)	Domestic (IHS(In House))
33. 531848	TIBC / UIBC	- R1 (-) - TIBC / UIBC buffer pH = 8.0 (220 mmol/l) - Guanidine hydrochloride (04 M) - Hydroxylamine (255 mmol/l) - Thiourea (80 mmol/l) - R2 (-) - Sodium Acetate (170 mmol/l) - Ferrozine (42 mmol/l) - R3 (-) - Iron Saturating Solution (-)	Domestic (IHS(In House))
34. 548017	Total Protein	- Cupric Sulphate (7 mMol/L) - Pot. Iodide (6 mMol/L) - Tartarate (20 mMol/L) - Surfactant (Triton-X 100) (0.05 % W/V)	Domestic (IHS(In House))
35. 548018	Triglycerides	- Goods buffer ; pH 7.2 (50 mMol/L) - Lipase (150 KU/L) - Glycerol kinase (55 IU/L) - Glycerol Phosphate Oxidase (5 KU/L) - Peroxidase (50 IU/L) - ATP * (1 mMol/L) - Chromogens (2 mMol/L)	Domestic (IHS(In House))
36. 532221	UREA	- Phosphate Buffer pH 7.0 (35 mMol/L) - Urease (15 KU/L) - Phenolic Chromogen (2 mMol/L) - Hypochlorite (4 mMol/L)	Domestic (IHS(In House))
37.	Urea Nitrogen (BUN)		Domestic (IHS(In House))

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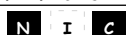
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548010	- Tris Buffer pH 8.0 (150 mMol/L) - α - ketoglutarate (10 mMol/L) - NADH * (0.25 mMol/L) - ADP * (2 mMol/L) - Urease (10 KU/L) - Glutamate dehydrogenase (900 U/L)	
38. Uric Acid 548019	- Goods buffer (100 mMol/L) - Peroxidase (140 IU/L) - Uricase (25 IU/L) - Chromogen (2.5 μ Mol/L)	Domestic (IHS(In House))

PAN No.	Staff Name	Section	Designation	Qual
AFFPJ9092P	BHAVANA H. JOSHI	Chemical & Instrumentation	QC CHEMIST	BSC
AAAPD9083A	MAHENDRA DASHORA	Diagnostic Reagents	DIRECTOR	BSC

This License has been renewed on 07/03/2016 and valid up to 06/03/2021

Terms and Conditions

- 1) Licensee should comply with all the provisions of Drugs & Cosmetics Act, 1940 & Rules 1945 as amended up to dt.
- 2) Licensee should comply with all the provisions of Drugs (Price Control) Order 2013 as amended up to dt (wherever applicable).
- 3) Licensee should abide by all the provisions of Drugs & Magic Remedies (Objectionable Advertisement) Act, 1954 & Rules 1955 as amended up to date
- 4) Licensee should not manufacture any drug/cosmetic by a name belonging to another manufacturer
- 5) Licensee should not manufacture or sell drugs/cosmetics even if it is included in the approved list of product, if it is or as and when banned by Licensing Authority or Drugs Controller General of India or Government of India.
- 6) The permission is granted subject to the condition that, the product is safe, for use in context of pharmaceutical Aids, Additions and excipient used in the formulation
- 7) Any addition thereto or any deletion therefore will not be carried out without permission of Licensing Authority



VIRAJ TUKARAM PAUNIKAR
e-Signed on 04-11-2016 23:31
(Organic Authentication on AADHAR from UIDAI Server)
TPAV # 9T7ESVHUFK



V.T Paunikar
Licensing Authority
Food & Drugs Administration
KONKAN Division, Maharashtra State

Applicant :

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I/IV) KOLGAON, PALGHAR - 401404
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