

Schedule of Accreditation
for Testing Laboratory According to ISO/IEC 17025
Quality Control Laboratory
Amriya Pharmaceutical Industries
Amriya, Alexandria –Cairo Deseret Rord KM 25

CAB NO.: 216034 B

1st Accreditation date: December 28, 2017

Issue No. (1): December 28, 2017

Revision No. (1) November 6, 2018

Valid to: October 30, 2020

Materials / Products Tested	Types of Tests / Properties Measured / Range of Measurements	Standard Specifications / Techniques Used	
Dexamethazone ampoule	Assay by HPLC	SOP Code No. D1-82-0605/1/R&S Based on EP 9.2	HPLC MODEL SHIMADZU CODE QFB02&QRM22 Balance Model TE 2145 S.N. :23903692
	Determination of pH	USP40-NF 35	pH Meter Model 3510 S.N. 1563
dexamethasone sodium phosphate	Assay by HPLC	EP 9.2	HPLC MODEL SHIMADZU CODE QRM 22

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كورنيش المعادي - برج رياض المعادي ١ - القاهرة - مصر

تليفون : ٢٥٢٧٥٢٢٠/٥/٦/٧ (٢٠٢)

فاكس : ٢٥٢٧٥٢٢٤ (٢٠٢)

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<u>Suppositories</u> Amriphylline Adult Suppositories, Amriphylline Pediatric Suppositories, Amrizole N Vaginal Suppositories, Amrizole Rectal Suppositories, Amrizole Vaginal Suppositories, Bisadyl Adult, uppositories, Bisadyl Pediatric Suppositories, Ketofan Suppositories, Meloxicam Suppositories, Micoban Vaginal Suppositories, Paragesic Suppositories, Procto-Lidosine Suppositories, Rectoplexil Suppositories. <u>Oral solutions</u> Amriphlline syrup, Amrizole Suspension, Bisadyl Enema, Carbolase Syrup, Decal B12 Syrup, Histazine -1 Drops, Histazine -1 Syrup, Immunvita Drops, Ketofan Suspension, Micoban Solution, Nifunal Suspension, Oplex Syrup, Otosept Ear Drops, Paracetamol Suspension, Primalan Syrup, Smacta 60 ml Suspension, Smacta 90 ml Suspension, Smacta 120 ml Suspension, Tanakan Solution.	Total aerobic microbial count Total Yeast & mould count	USP- 40-NF 35 :2017 (Chapter 61)	Vertical LAF Model Aura vertical SD4 S.N.L02Q07N4685
	Detection and Enumeration of a) <i>Staphylococcus aureus</i> b) <i>Eschrichia coli</i> c) <i>Candida albicans</i>	USP 40-NF 35:2017 (Chapter 62)	Incubater Model HERAUS , S.N 9610414 Model MEMMERT, S.N E704.0008 Model PROLABO, S.N 38802186 Autoclave Model MATACHANA Sterilizer S.N.N.A Autoclave Model STERIS Steam Sterilizer S.N. 032621121

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فاكس : ٢٥٢٧٥٢٢٤ (٢٠٢)

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<u>Solid dosage form</u> Alucal Tablets, Alucal Plus Tablets, Amlodipine 10 mg Tablets, Amlodipine 5 mg Tablets, Amrase Tablets, Amriflucan Capsules, Amristatin Tablets, Amrizole 250 mg Tablets, Amrizole 500 mg Tablets, Azrolid Tablets, Bisadyl Tablets, Bromhexine Tablets, Cafamol Extra Tablets, Carbolase Capsules, Clarithro 250 mg Tablets, Clarithro 500 mg Tablets, Diet Sweet 100 Tablets, Diet Sweet 350 Tablets, Diet Sweet 50 Tablets, Diet Sweet Powder, Dioven 150 mg Tablets, Dioven 500 mg Tablets, Diurex Tablets, Estohalt 10 Capsules, Estohalt 40 Capsules, Flexofan Capsules, Glipicrone Tablets, Histazine-1 Tablets, Hysartan Tablets, Ketofan 100 SR Capsules, Ketofan 200 SR Capsules, Ketofan 75 Capsules, Ketofan Tablets, Ketolac Tablets, L-Carnitine Tablets, Losartan 50 mg Tablets, Meloxicam Tablets, Micoban Powder, Microserc 16 Tablets, Microserc 24 Tablets, Microserc Tablets, Nifunal Capsules, Primalan Tablets, Smecta Powder, Spasmo-Amrase Tablets, Spasmotalin Forte Tablets, Spasmotalin Tablets, Tamoxifen 10 mg Tablets, Tamoxifen 20 mg Tablets, Tanakan Tablets, Theophylline SR Tablets, Vinporal Tablets, Xinase Capsules	Total aerobic microbial count Total Yeast & mould count	USP- 40-NF 35:2017 (Chapter 61)	Vertical Laminar Flow Model Aura vertical SD4 S.N L02Q07N4685 Incubater Model HERAUS, S.N 9610414 Model MEMMERT, S.N E704.0008 Model PROLABO, S.N38802186 Model MATACHANA Sterilizer S.N.N.A Autoclave Model STERIS Steam Sterilizer S.N. 032621121
	Detection and Enumeration of a) <i>Staphylococcus aureus</i> b) <i>Eschrichia coli</i> c) <i>Candida albicans</i>	USP 40-NF 35:2017 (Chapter 62)	

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<u>Oral solutions</u> Amriphylline Syrup, Amrizole Suspension, Bisadyl Enema, Bromhexine Syrup, Carbolase Syrup, Decal B12 Syrup, Histazine - 1 Drops, Histazine -1 Syrup, Immunvita Drops, Ketofan Suspension, Micoban Solution, Nifunal Suspension, Oplex Syrup, Otosept Ear Drops, Paracetamol Suspension, Primalan Syrup, Smacta 60 ml Suspension, Smacta 90 ml Suspension, Smacta 120 ml Suspension, Tanakan Solution <u>Semi-Solid Dosage Form</u> Baby Guard Cream, Betamethasone Cream, Betamethasone Ointment, Betnosal Ointment, Betapanthen cream, Clovacort Cream, Clovacort Gel, Clovacort Ointment, Dexpanthenol Cream, Ketofan Gel, Lidocaine Ointment, Micoban Cream, Micoban Oral Gel, Micosone Cream, NP Cream, NPB Ointment, Procto-Lidocaine Cream	Total aerobic microbial count Total Yeast & mould count	USP- 40-NF 35:2017 (Chapter 61)	Vertical Laminar Flow Model Aura vertical SD4 S.N L02Q07N4685 Incubater Model HERAUS , S.N 9610414 Model MEMMERT, S.N E704.0008 Model PROLABO, S.N 38802186 Model MATACHANA Sterilizer S.N.N.A Autoclave Model STERIS Steam Sterilizer S.N. 032621121
	Detection and Enumeration of a) <i>Staphylococcus aureus</i> b) <i>Escherichia coli</i> c) <i>Candida albicans</i>	USP 40-NF 35:2017 (Chapter 62)	

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فاكس : ٢٥٢٧٥٢٢٤ : (٢٠٢)

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<u>Ampoules (bioburden test)</u> Alambuphine Ampoules, Amri-K Ampoules, Depovit B12 Ampoules, Dexamethasone Ampoules, Haemopower Ampoules, Haemojet Ampoules, ketofan ampoules, Ketolac Ampoules, Meloxicam Ampoules, Neostigmine Ampoules, Neurovit Ampoules, Spasmofen Ampoules, Tramadol Ampoules, Vinporal Ampoules, Shancita Ampoules. <u>Injectable Vial (Bioburden Test)</u> Amrizole vial, Ciprofloxacin Vial, Injectamol Vial	Total aerobic microbial count Total Yeast & mould count	USP- 40-NF 35 :2017 (Chapter 61)	Vertical LAF Model Aura vertical SD4 S.N L02Q07N4685 Incubater Model HERAUS ,S.N 9610414 Model MEMMERT, S.N E704.0008 Model PROLABO, S.N 38802186 Model MATACHANA Sterilizer S.N.N.A Autoclave Model STERIS Steam Sterilizer S.N. 032621121
	Tests for specified microorganisms Detection and Enumeration of a) <i>Staphylococcus aureus</i> b) <i>Eschrichia coli</i> c) <i>Candida albicans</i> d) <i>Pseudomonas aeruginosa</i> e) <i>Salmonella species.</i>	USP 40-NF 35:2017 (Chapter 62)	

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فاكس : ٢٥٢٧٥٢٢٤ (٢٠٢)

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Raw Materials Arginine base, anhydrous, Avicel RC591, (Viva Pure MCG 58/P), Azithromycin Dihydrate powder, Beclomethasone dipropionate, Bees wax, white, Benzocaine, Benzoyl metronidazole, Betamethasone dipropionate, Betamethasone valerate, Bran Radiated, Butylated Hydroxy Anisol (Tenox), Bromhexine hydrochloride, Budesonide, Cloperastin fendizoate, Calcium levulinate, Calcium Folate, Carbocisteine, Carbopol NF 940, Carbopol PNF 934 (Carbomer 934 P), Cetirizine Dihydrochloride, Ceftriaxone, Ciprofloxacin base, Citric acid anhydrous (pyrogen free), Citric acid monohydrate (pyrogen free), CMC sodium (walocel) 1000 GA, CMC sodium (walocel) 10000 PA, Colour caramel, Colour ponceau 4R E-124, Colour quinoline yellow, Colour sunset yellow 85%, Cremophore A6, Cremophore A25 (Polyoxyethylene Cetosteryl Ether), Cremophore RH40, Cremophore EL, Crodacol C90 (Lanette 16) (cetyl alcohol), Calcium Gluconate, Calcium Lactate, Clindamycin Phosphate, Cloperastin HCL, Citicoline sodium, Cyanocobalamin (Vitamin B12).	Total aerobic microbial count Total Yeast & mould count	USP- 40-NF 35 :2017 (Chapter 61)	Vertical Laminar Flow Model Aura vertical SD4 S.N L02Q07N4685 Incubater Model HERAUS, S.N 9610414 Model MEMMERT, S.N E704.0008 Model PROLABO, S.N 38802186 Model MATACHANA Sterilizer S.N.N.A Autoclave Model STERIS Steam Sterilizer S.N. 032621121
	Detection and Enumeration of a) <i>Staphylococcus aureus</i> b) <i>Escherichia coli</i> c) <i>Candida albicans</i>	USP 40-NF 35:2017 (Chapter 62)	

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<u>Raw Materials</u> Dehymulus E, Dexamethasone sodium phosphate, Dexpanthenol, Dimethicone 350P (Silicon Fluid), Dioctahedral smectite, Dextrose monohydrate, Echinaceae purpureae powder, Flavour Anise (24047), Flavour Cherry Powder P102, Flavour banana 10 842951 "Iff", Flavour banana Powder P102, Flavour caramel, Flavour cherry 218904 H&R, Flavour cherry EXE 04691 IFF, Flavour Tutti frutti, BC 101 "Kamina", Flavour Lavander WB50, Fluconazole, Ginkgo biloba extract, Glycerol (Glycerine), Glyceryl mono-stearate (cutina GMS), Guaiphenesine, Hydrocortisone acetate, Hydrogenated glucose syrup (lycasin 80/55), Hydroxocobalamine acetate, Hyoscine N-butyl bromide, Iron Sucrose powder, Iron Sucrose solution, Iron polymaltose, Ketoprofen Powder, Ketrolac tromethamine, Lactic acid, Lactose-DC-21 Anhydrous, Lidocaine (lignocaine) base, Lidocaine (lignocaine) hydrochloride, Lactose monohydrate 200 M, Lactose monohydrate For Tableting (Merc), L-carnitine base Meloxicam, Metronidazole, Miconazole nitrate, Methocel (H.P.M.C) 15CPS, 6CP, Metformine hydrochloride, Mometasone furate monohydrate, Mannitol	Total aerobic microbial count Total Yeast & mould count	USP- 40-NF 35:2017 (Chapter 61)	Vertical Laminar Flow Model Aura vertical SD4 S.N: L02Q07N4685 Incubater Model HERAUS , S.N 9610414 Model MEMMERT, S.N E704.0008 Model PROLABO, S.N 38802186 Model MATACHANA Sterilizer S.N.N.A Autoclave Model STERIS Steam Sterilizer S.N. 032621121
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<u>Raw Materials</u> Neostigmine methyl sulphate, Nifuroxazide, Nalbuphine hydrochloride, Narcotan, Nivea Fragrance FRG, Oleic acid, Oxycodone Hydrochloride, Ovucire WL 3264, Oxomemazine base, Paracetamol, Paraffin liquid (vara 200), Petrolatum white (vara 4415) (Paraffin Soft White), Phenazone (antipyrine), Phytomenadione (Vitamin K), Polawax GP 200, Poloxamer 407 (Lutrol F127), Polyethylene glycol (Macrogol 4000, 1400- 1550), Polyethylene glycol (Macrogol 6000), Potassium ferrocyanide, Propylene glycol, Pseudophedrine HCl, Potassium Chloride, Potassium Bicarbonate, Pyridoxine HCl, Saccharine sodium, Semithicone emulsion, Sodium acetate trihydrate Pyrogen free, Sodium chloride Pyrogen free, Sodium citrate dehydrate Pyrogen free, Sodium dibasic phosphate: pyrogen free, Sodium edetate Pyrogen free, Sodium metabisulphite (pyrosulphite) Pyrogen free, Sodium phosphate monobasic Pyrogen free, Sodium sulphite Pyrogen free, Sorbic Acid, Steryl Alcohol S95 (Crodacol S95), Sodium Bicarbonate,	Total aerobic microbial count Total Yeast & mould count	USP- 40-NF 35:2017 (Chapter 61)	Vertical Laminar Flow Model Aura vertical SD4 S.N L02Q07N4685 Incubator Model HERAUS , S.N 9610414 Model MEMMERT, S.N E704.0008 Model PROLABO, S.N 38802186 Model MATACHANA Sterilizer S.N.N.A Autoclave Model STERIS Steam Sterilizer S.N. 032621121
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<u>Raw Materials</u> Sodium phosphate Tribasic Anhydrous, Sorbitol solution 70% (non-Crystalline), Sorbitol solution 70/20 (Crystalline), Sucralose, Sucrose, Thiamine HCl (Vitamin B1), Tramadol hydrochloride, Triethanolamine, Tartaric Acid, Tripolidine HCl, Vanillin, Veegum HV, Vitamin D3 powder 40 M.I.U, Volpo CS 20, Wool fat (Lanoline Crona), Witepsol S55, Xanthan gum (Keltrol RD), Xylitol, Zinc oxide <u>Packaging Materials</u> Empty bottles (plastic bottles , plastic jars and of glass bottles), Plastic containers (droppers ,pilfer proof Caps, aluminum tubes, applicators, syringes, caps, sliders and boxes), PVC, PVDC, Aluminum Foil and Soft Aluminum foil & PVC/PE and PVC/PVDC& Triplex PVC/PE PV, For Sliders ,desiccants and rubber stoppers For Vial 100 ml and Sprayers	Total aerobic microbial count Total Yeast & mould count	USP- 40-NF 35:2017 (Chapter 61)	Vertical Laminar Flow Model Aura vertical SD4 Serial number: L02Q07N4685 Incubater Model HERAUS, S.N 9610414 Model MEMMERT, S.N E704.0008 Model PROLABO, S.N 38802186 Model MATACHANA Sterilizer S.N.N.A Autoclave Model STERIS Steam Sterilizer S.N. 032621121
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