

<b>Laboratory</b>	<b>Akums Drugs and Pharmaceuticals Ltd. Plant-1, Quality Control Laboratory, 19-20-21, Sector-6A, I.I.E., SIDCUL, Ranipur, Haridwar</b>		
<b>Accreditation Standard</b>	<b>ISO/IEC 17025: 2005</b>		
<b>Discipline</b>	<b>Biological Testing</b>	<b>Issue Date</b>	<b>04.09.2013</b>
<b>Certificate Number</b>	<b>T-1998</b>	<b>Valid Until</b>	<b>03.09.2015</b>
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<b>S.No.</b>	<b>Product / Material of Test</b>	<b>Specific Test Performed</b>	<b>Test Method Specification against which tests are performed</b>	<b>Range of Testing / Limits of Detection</b>
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## **I. DRUGS & PHARMACEUTICALS**

### **A. General Tests of Biological Testing for Pharmaceutical Dosage Forms**

<b>1. Pharmaceutical Dosage Like Tablet, Capsules, Dry Syrup and Oral Suspension</b>	Total aerobic microbial count/ Viable bacterial count (By Pour plate method)	IP 2010 BP 2013 USP35 NF30	≥ 1 CFU/mL ≥ 10 CFU/ g
	Test for specific organism [ <i>Escherichia coli</i> , <i>Salmonella</i> , <i>S.aureus</i> , <i>P.aeruginosa</i> ] (By Direct inoculation)	IP 2010 BP 2013 USP35 NF30	Present/1mL or1g Absent /1mL or1g

### **B. Finished Product Having Specific Test of Biological Testing**

<b>1. Ferrous Fumerate, Folic Acid, Vitamin C, Vitamin B12, Zinc Sulphate Capsules</b>	Assay of Folic acid	GTP No.: AQC-097	*Not less than 50% *Not More than 200%
	Assay of Vitamin B12	GTP No.:AQC-098	*Not less than 50% *Not More than 200%
<b>2. Alpha Lipoic Acid, Pyridoxine, Methylcobalamin, Folic Acid, Selenium Capsules</b>	Assay of Folic Acid	GTP No.: AQC-097	*Not less than 50% *Not More than 200%
	Assay of Methylcobalamin	GTP No.: AQC-100	*Not less than 50% *Not More than 200%
<b>3. Amoxicillin, Dicloxacillin &amp; Lactic acid Capsules</b>	Assay of Lactic Acid Bacillus	GTP No.: AQC-101	*Not less than 50% *Not More than 200%

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4.	<b>Cefixime, Diocloxacin &amp; Lactic acid bacillus Tablets</b>	Assay of lactic acid bacillus	GTP No.: AQC-101	*Not less than 50% *Not More than 200%
5.	<b>Cefpodoxime Proxetil &amp; Lactic Acid Bacillus Dispersible Tablets</b>	Assay of lactic acid bacillus	GTP No.: AQC-101	*Not less than 50% *Not More than 200%
6.	<b>Cefuroxime Axetil &amp; Lactic Acid Bacillus Tablets</b>	Assay of lactic acid bacillus	GTP No.: AQC-101	*Not less than 50% *Not More than 200%
7.	<b>Gabapentin &amp; Mecobalamin Tablets</b>	Assay of Mecobalamin	GTP No.: AQC-100	*Not less than 50% *Not More than 200%
8.	<b>Ginseng Extract Vitamin A, Vitamin E, Vitamin D3 Vitamin B1-12, Calcium Pantothenate, Niacinamide, Vitamin C, Folic Acid, Biotin, Iron, Zinc, Magnesium Oxide, Manganese, Copper, Iodine, Capsules</b>	Assay of Vitamin B12	GTP No.: AQC-098	*Not less than 50% *Not More than 200%

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9.	<b>Ginseng Extract, Thiamine Mononitrate, Riboflavin , Pyridoxine hydrochloride, Methylcobalamin, Niacinamide, Calcium Pantothenate, Folic Acid, Ascorbic Acid, Zinc Sulfate Monohydrate, Calcium Hydrogen Phosphate, elemental phosphorous Potassium Iodide &amp; Ferrous Fumarate capsules</b>	Assay of Methylcobalamin	GTP No.: AQC-100	*Not less than 50% *Not More than 200%
		Assay of Folic acid	GTP No.: AQC-097	*Not less than 50% *Not More than 200%
10.	<b>Green Tea, Lutein, Choline Bitartrate, Vitamin A, Vitamin D3, Vitamin E, Vitamin K Vitamin B1-12, Niacinamide, Vitamin C, Folic Acid, Biotin, Calcium Fumarate, Zinc, Iodine, Magnesium, Manganese, Copper, Chromium, Molybdenum, Selenium, Boron, Nickel, Tin, Vanadium Capsules</b>	Assay of Vitamin B12	GTP No.: AQC-098	*Not less than 50% *Not More than 200%

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11.	<b>Ofloxacin, Ornidazole &amp; Lactic Acid Bacillus Tablets</b>	Assay of Lactic acid bacillus	GTP No.: AQC-101	*Not less than 50% *Not More than 200%
12.	<b>Pregabalin, Alpha Lipoic Acid, Vitamin B6, Folic Acid &amp; Methylcobalamin Capsules</b>	Assay of Folic acid Assay of Methylcobalamin	GTP No.: AQC-097 GTP No.: AQC-100	*Not less than 50% *Not More than 200% *Not less than 50% *Not More than 200%
13.	<b>Thiamine, Riboflavin, Pyridoxine, Methylcobalamin, Niacinamide, Calcium, Folic Acid, Ascorbic, L-Glutamic Acid, Biotin, Copper, Manganese, Zinc, Selenium, Chromium &amp; Molybdate, Magnesium Tablets</b>	Assay of Methylcobalamin	GTP No.: AQC-100	*Not less than 50% *Not More than 200%
14.	<b>Soft gelatin capsule containing Omega-3 Fatty Acids, Chromium Picolinate, Wheat Germ Oil, Menadione sodium isulphaite, Biotin Potassium Iodide, Vitamin B12 Sodium Molybdate Dihydrate Sodium Selenite Pentahydrate</b>	Assay of Vitamin B12 Assay of Folic acid Assay of Lactic acid bacillus	GTP No.: AQC-098 GTP No.: AQC-097 GTP No.: AQC-101	*Not less than 50% *Not More than 200% *Not less than 50% *Not More than 200% *Not less than 50% *Not More than 200%

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Potassium Chloride, Sodium Borate, Nickel Sulfate, Vitamin B6, Vitamin - D3, Copper Sulfate Pentahydrate, Folic acid	Assay of Vitamin B12	GTP No.: AQC-098	*Not less than 50% *Not More than 200%
	Choline Bitartrate, Colloidal Silicon Dioxide Stannous Chloride Dehydrate, Sodium Netavanadate, Green Tea Extract, Ginseng Extract, Ginkgo Biloba Extract, Grape Seed Extract, Magnesium Oxide, Benfothiamine, Citrus Bioflavonoids, Natural Mixed Carotenoids Lutein, Lactic acid bacillus, iperine, Ferrous Fumarate, Zinc Oxide, Niacinamide, Manganese Sulfate, Calcium Ascorbate, Dibasic calcium phosphate	Assay of Folic acid	GTP No.: AQC-097	*Not less than 50% *Not More than 200%
		Assay of Lactic acid bacillus	GTP No.: AQC-101	*Not less than 50% *Not More than 200%

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\* Note-Limits are specified as per the Label Claim.