

## Testing Laboratory

Accreditation Scope of Efroz Chemical Industries (Pvt.) Ltd., Karachi, Pakistan

### Permanent laboratory premises

<b>Materials/ Products tested</b>	<b>Types of test/ Properties measured</b>	<b>Range of measurement</b>	<b>Minimum detection limit</b>	<b>Uncertainty of Measurement (where applicable) MU (±)</b>	<b>Standard specification/ Techniques/ equipment used</b>
Eftran Tablets & Eftran DS Tablets	Weight Variation (Uniformity of weight)	575mg -1165mg	1.0 mg	3.00 mg	Standard Method BP 2007, Vol-IV /Weighing on analytical Balance,
	Disintegration Time	NMT 15 min	02 sec	1 mint	Standard Method BP 2007, Vol-IV Visual evaluation/ Dis. App. Electro lab ED- 2L
	Moisture Test	0.2% - 2.5 %		0.06 %	Standard Method BP 2007, Vo 1- IV /Karl Fischer Titration
	Assay of Sulphamethoxazole	90.0% ---110.0% of label claimed	10.0 %	1.48 %	Standard Method USP -29
	Assay of Trimethoprim	90.0% -110.0% of label claimed	10.0 %	2.44 %	Chromatographic Separation/ HPLC Shimadzu
<i>Erizole 100mg Tablets &amp; Erizole 500mg Tablets</i>	Weight Variation (Uniformity of weight)	265mg –300mg	0.10 mg	3.00 mg	Standard Method BP 2007, Vol-IV /Weighing on analytical Balance,
	Disintegration Time	NMT 15 min	02 sec	1 mint	Standard Method BP 2007, Vol-IV Visual evaluation/ Dis. App. Electro lab ED- 2L
	Moisture Test	2.0% –5.0 %	0.01 %	0.06 %	Standard Method/Karl BP 2007, Vol-IV Fischer Titration/
	Assay of Mebendazole	90.0---110.0% of label claimed	10.0 %	2.59 %	Standard Method/ USP-29 Chromatographic Separation/ HPLC Shimadzu
<i>Erizole Suspension</i>	pH value in liquid	4 – 7	2	0.1	Standard Method BP 2007, Vol-IV/ Mettler Toledo MP-220 pH Meter
	Total aerobic Count	NMT 1000 cfu/ml	10 cfu/ml	Not Applicable	Standard Method BP 2007, Vol-IV /Incubators WTC Binder/ Nutritional media
	Total fungus Count	NMT 100 cfu/ml	10 cfu/ml	Not Applicable	Standard Method BP 2007, Vol-IV /Incubators FTC 90-E/ Nutritional media

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<i>Erizole Suspension</i>	Absence of <i>Salmonella</i> sp.	Must be absent per 10 ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV/ Incubators Lab Tech Korea, /Selective media
	Absence of <i>Escherichia coli</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV/ Incubators, Lab Tech Korea /Selective media,
	Absence of <i>Staphylococcus Aureus</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV / Incubators Lab Tech Korea, Selective media
	Absence of <i>Pseudomonas aeruginosa</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV / Incubators Lab Tech Korea, selective media.
Glicon Tablets & Semi Glicon Tablets	Weight Variation (Uniformity of weight)	97mg - 172 mg	1.0 mg	3.00 mg	Standard Method BP 2007, Vol-IV /Weighing on analytical Balance,
	Disintegration Time	NMT 15 min	02 sec	Not Applicable	Standard Method BP 2007, Vol-IV Visual evaluation/ Dis. App. Electro lab ED-2L
	Moisture Test	4.0 % - 10.0 %	0.01 %	0.06 %	Standard Method BP 2007, Vol-IV / Karl Fischer Titration/
	Assay of Glibenclamide	95.0% -105.0% of label claimed	10.0 %	1.88 %	Standard Method BP-2007 Vol-111 Chromatographic Separation/HPLC Shimadzu
<i>Isotab 20 Tablets &amp; Isotab 40 Tablets</i>	Weight Variation (Uniformity of weight)	157mg - 183 mg	0.10 mg	3.00 mg	Standard Method BP 2007, Vol-IV /Weighing on analytical Balance,
	Disintegration Time	NMT 15 min	01 sec	Not Applicable	Standard Method BP 2007, Vol-IV Visual evaluation/ Dis. App. Electro lab ED-2L
<i>Mefnac Tablets &amp; Mefnac DS Tablets</i>	Weight Variation (Uniformity of weight)	570mg - 647 mg	1.0 mg	3.00 mg	Standard Method BP 2007, Vol-IV /Weighing on analytical Balance,
	Disintegration Time	NMT 15 minutes	0.2 Sec	1 mint	Standard Method, BP 2007, Vol-IV Visual evaluation/ Dis. App. Electro lab ED-2L

Date

Director

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<i>Mefnac Tablets &amp; Mefnac DS Tablets</i>	Moisture Test	3.0% –5.0 %	0.01 %	0.06 %	Standard Method BP 2007, Vo I- IV /Karl Fischer Titration
	Assay of Mefenamic Acid	95.0%--105.0 % of label claimed	30.0 %	3.68 %	Standard Method BP 2007, Vol-IV Titration technique, Burette
<i>Maladar Suspension</i>	Total aerobic Count	NMT 1000 cfu/ml	10 cfu/ml	Not Applicable	Standard Method BP 2007, Vol-IV /Incubators WTC Binder/ Nutritional media
	Total fungus Count	NMT 100 cfu/ml	10 cfu/ml	Not Applicable	Standard Method BP 2007, Vol-IV /Incubators FTC 90-E/ Nutritional media
	Absence of Salmonella sp.	Must be absent per 10 ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV/ Incubators Lab Tech Korea, /Selective media
	Absence of <i>Escherichia coli</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV/ Incubators, Lab Tech Korea /Selective media,
	Absence of <i>Staphylococcus Aureus</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV / Incubators Lab Tech Korea, Selective media
<i>Metphage 500mg Tablets &amp; Metphage 850 mg Tablets</i>	Absence of <i>Pseudomonas aeruginosa</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV / Incubators Lab Tech Korea, selective media.
	Weight Variation (Uniformity of weight)	589mg__966mg	1.0 mg	3.00 mg	Standard Method BP 2007, Vol-IV /Weighing on analytical Balance.
	Disintegration Time	NMT 15 min (Core) NMT 30 min (Coated)	02 sec	1 mint	Standard Method BP 2007, Vol-IV Visual evaluation/ Dis. App. Electro lab ED- 2L
	Moisture Test	1.5% –2.0 %	0.01 %	± 0.057 %	Standard Method BP 2007, Vo I- IV /Karl Fischer Titration
<i>Metphage 500mg Tablets &amp; Metphage 850 mg Tablets</i>	Assay of Metformin HCl	95.0%--105.0 % of label claimed	30.0 %	2.62 %	Standard Method BP 2007, Vol-IV /UV technique, Shimadzu UV-160 A

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	Dissolution of Metformin HCl	NLT 70.0% of label claimed	30.0 %	2 %	Standard Method BP 2007, Vol-III UV technique, Shimadzu UV-160 A
<i>Mefnac Suspension</i>	Total aerobic Count	NMT 1000 cfu/ml	10 cfu/ml	Not Applicable	Standard Method BP 2007, Vol-IV /Incubators WTC Binder/ Nutritional media
	Total fungus Count	NMT 100 cfu/ml	10 cfu/ml	Not Applicable	Standard Method BP 2007, Vol-IV /Incubators FTC 90-E/ Nutritional media
	Absence of Salmonella sp.	Must be absent per 10 ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV/ Incubators Lab Tech Korea, /Selective media
	Absence of <i>Escherichia coli</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV/ Incubators, Lab Tech Korea
	Absence of <i>Staphylococcus Aureus</i>	Must be absent per ml	Qualitative	Not Applicable	/Selective media, Standard Method BP 2007, Vol-IV / Incubators Lab Tech Korea, Selective media
	Absence of <i>Pseudomonas aeruginosa</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV / Incubators Lab Tech Korea, selective media.
	Assay of Mefenamic	95-110% of label claimed	90 %	0.93 %	In-House method UV photometer
<i>Metcon Tablets , Metcon plusTablets &amp; Semi Metcon Tablets</i>	Assay of Metformin HCl	90.0%---110.0% of label claimed	95.0%	2.62%	Validated Method Chromatographic Separation & UV Spectrophotometer/ HPLC Shimadzu & Shimadzu UV-160 A
	Assay of Glibenclamide	90.0%---110.0% of label claimed	95.0%	1.88%	
<i>Pango 200mg Tablets &amp; Pango 400mg Tablets</i>	Assay of Ibuprofen	95% -105% of label claimed	95 %	0.83 %	Standard Method HPLC Technique, BP 2007, Vol-I
Panaram Tablets	Weight Variation (Uniformity of weight)	577.6mg - 638.4 mg	1.0mg	3.00 mg	Standard Method BP 2007, Vol-IV / Weighing on analytical Balance

Materials/ Products tested	Types of test/ Properties measured	Range of measurement	Minimum detection limit	Uncertainty of Measurement (where applicable) MU (±)	Standard specification/ Techniques/ equipment used
Panaram Tablets	Disintegration Time	NMT 15 min	02sec	1 mint	Standard Method BP 2007, Vol-IV Visual evaluation/ Dis. App. Electro lab ED- 2L
	Moisture Test	1.5 % – 3.0 %	0.01%	0.057%	Standard Method/Karl BP 2007, Vo 1- IV Fischer Titration/ Standard Method BP 2007, Vol-1II UV technique, Shimadzu UV-160
	Assay of Paracetamol	95.0 % - 105.0 % Of label claimed	30.0 %	1.9%	
Panaram Suspension	pH value in liquid	5 – 7	0.01	0.01	Standard Method BP 2007, Vol-IV/ Mettler Toledo MP-220 pH Meter
Roxin 250 mg Tablets & Roxin 500 mg Tablets	Weight Variation (Uniformity of weight)	361mg – 811 mg	0.10 mg	3.00 mg	Standard Method BP 2007, Vol-IV /Weighing on analytical Balance
	Disintegration Time	NMT 15 min (Core) NMT 30 min (Coated)	01 sec	N/A	Standard Method BP 2007, Vol-IV Visual evaluation/ Dis. App. Electro lab ED- 2L
	Moisture Test	1 % - 7.5 %	0.01%	0.06 %	Standard Method BP 2007, Vol-IV /Karl Fischer Titration/ Standard Method USP -29 Chromatographic Separation/ HPLC Shimadzu
Siam Suspension	Assay of Ciprofloxacin	90.0 % - 110.0 % of label claimed	50.0 %	0.23 %	
	pH value in liquid	7.0-8.6	2	0.1	Standard Method BP 2007, Vol-IV/ Mettler Toledo MP-220 pH Meter
	Total aerobic Count	NMT 1000 cfu/ml	10 cfu/ml	Not Applicable	Standard Method BP 2007, Vol-IV /Incubators WTC Binder/ Nutritional media
	Total fungus Count	NMT 100 cfu/ml	10 cfu/ml	Not Applicable	Standard Method BP 2007, Vol-IV /Incubators FTC 90-E/ Nutritional media
	Absence of Salmonella sp.	Must be absent per 10 ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV/ Incubators Lab Tech Korea, /Selective media
	Absence of <i>Escherichia coli</i>	Must be absent per ml	Qualitative	Not Applicable	Standard Method BP 2007, Vol-IV/ Incubators, Lab Tech Korea /Selective media

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Siam Suspension	Absence of <i>Staphylococcus Aureus</i>  Absence of <i>Pseudomonas aeruginosa</i>	Must be absent per ml  Must be absent per ml	Qualitative  Qualitative	Not Applicable  Not Applicable	Standard Method BP 2007, Vol-IV / Incubators Lab Tech Korea, Selective media Standard Method BP 2007, Vol-IV / Incubators Lab Tech Korea, selective media
Zetrine Syrup	pH value in liquid	4-5	2	0.1	Standard Method BP 2007, Vol-IV / Mettler Toledo MP-220 pH Meter
Pango Suspension 100mg/5ml	Assay of Ibuprofen	95 % - 105 % of label claimed	95 %	0.99 %	Standard Method HPLC Technique, BP 2007, Vol-I
Klabid Tablets 250mg & Klabid Tablets 500mg	Assay of Clarithromycin	95-110 % of label claimed	90 %	0.23 %	Standard Method HPLC Technique, BP 2007, USP-28
Packaging components of all products	Dimension of Unit Carton L x W x H  Leaflet & Labels L x W  Al. foil, PVC, Cold forming L&T	13 mm – 250 mm	01 mm	0.2 mm	In-House method
Packaging components of all products	Grammage of Unit Carton,  Leaflet & Label  Al. foil,  PVC, Cold forming	50 g/m <sup>2</sup> – 350 g/m <sup>2</sup>	10 g/m <sup>2</sup>	0.85 g/m <sup>2</sup>  0.66 & 0.44 g/m <sup>2</sup>  0.03 g/m <sup>2</sup>  0.76 g/m <sup>2</sup>	In-House method
Packaging components	Brimful Capacity of Glass bottles	30 ml – 145 ml	1 ml	0.2 ml	In-House method
<b>Extension of Scope (07 Sep 2010)</b>					
Isotab-20 Tablets Isotab-40 Tablets & Isotab-XR Tablets	Assay of Isosorbide-5- Mononitrate	95.0 % - 105.0 % of label claimed	10.0%	1.48 %	Standard Method BP 2010 Chromatographic Separation/ HPLC Shimadzu
Corbis 2.5mg Tablets, Corbis 5.0mg Tablets & Corbis 10mg Tablets	Assay of Bisoprolol Fumarate	90.0 % - 105.0 % of label claimed	10.0%	1.14%	Standard Method/ USP-29 Chromatographic Separation/ HPLC Shimadzu

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Panaram Tablets	Dissolution of Metformin HCl	NLT 70.0% of label claimed	20.0%	N/A	Standard Method BP 2010, Vol-III UV technique, Shimadzu UV-160 A
Tramapar Tablets	Assay of Paracetamol  Assay of Tramadol	90.0 % - 110.0 % of label claim  90.0 % - 110.0 % of label claim	0.10 mg  01 Sec	3.00mg  3.00mg	Validated Chromatographic Separation/ HPLC Shimadzu UV-160 A
E-zole Capsule 20mg & E-zole Capsule 40mg	Weight Variation (Uniformity of weight)  Assay of Esomeprazole	160 mg – 200 mg  90.0 % - 110.0 % of label claim	0.10 mg  10.0%	3.00mg  1.99%	Standard Method BP 2010, Vo I- IV /Weighing on analytical Balance  Validated Method Chromatographic Separation/ HPLC Shimadzu UV-160 A
Zetrine Syrup	Total Aerobic Count  Total Fungus Count  Absence of Salmonella sp.  Absence of Escherichia coli  Absence of Staphylococcus Aureus  Absence of Pseudomonas aeruginosa	NMT 100 cfu/ml  NMT 10 cfu/ml  Must be absent per 10 ml  Must be absent per ml  Must be absent per ml  Must be absent per ml	10 cfu/ml  10 cfu/ml  ----  ----  ----	5.06%  5.06%  Not Applicable  Not Applicable  Not Applicable  Not Applicable	Standard Method BP 2010, Vol-IV /Incubators WTC Binder/ Nutritional media Standard Method BP 2010, Vol-IV /Incubators FTC 90-E/ Nutritional media Standard Method BP 2010, Vol-IV/ Incubators Lab Tech Korea, /Selective media Standard Method BP 2010, Vol-IV/ Incubators, Lab Tech Korea /Selective media, Standard Method BP 2010, Vol-IV / Incubators Lab Tech Korea, Selective media Standard Method BP 2010, Vol-IV / Incubators Lab Tech Korea, selective media.

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Panaram Suspension	Total Aerobic Count	NMT 100 cfu/ml	10 cfu/ml	5.06%	Standard Method BP 2010, Vol-IV /Incubators WTC Binder/ Nutritional media
	Total Fungus Count	NMT 10 cfu/ml	10 cfu/ml	5.06%	Standard Method BP 2010, Vol-IV /Incubators FTC 90-E/ Nutritional media
	Absence of Salmonella sp.	Must be absent per 10 ml	----	Not Applicable	Standard Method BP 2010, Vol-IV/ Incubators Lab Tech Korea, /Selective media
	Absence of Escherichia coli	Must be absent per ml	----	Not Applicable	Standard Method BP 2010, Vol-IV/ Incubators, Lab Tech Korea /Selective media,
	Absence of Staphylococcus Aureus	Must be absent per ml	----	Not Applicable	Standard Method BP 2010, Vol-IV / Incubators Lab Tech Korea, Selective media
	Absence of Pseudomonas aeruginosa	Must be absent per ml	----	Not Applicable	Standard Method BP 2010, Vol-IV / Incubators Lab Tech Korea, selective media.

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