



ACCREDITATION DOCUMENT

F-06/02
Issue Date: 26/05/08
Rev. No: 05
LAB 029

Testing Laboratory

Accreditation Scope of Shaigan Pharmaceuticals Research & Testing Laboratories, 14-KM Adyala Road, Rawalpindi.

Permanent laboratory premises

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
Bexus 250 Tablets	Quantitative Analysis	0.206 – 22.1 µg/ml	0.068 µg/ml	0.02%	In house /Spectrophotometry/ Spectrophotometer
	Weighing	1 mg to 200 g	0.1 mg	0.01 %	USP/Weighing of material/Analytical balance
	Friability	0.05 %- 5 %	0.01%	0.01 %	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test	30 seconds to 99 minutes	1second	0.01 %	BP 2007/Disintegration/ Disintegration tester
Bexus 500 Tablets	Quantitative Analysis	0.206 – 22.1 µg/ml	0.068 µg/ml	0.02%	In house /Spectrophotometry/ Spectrophotometer
	Weighing	1 mg to 200 g	0.1 mg	0.01 %	USP/Weighing of material/Analytical balance
	Friability	0.05 %- 5 %	0.01%	0.01 %	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test	30 seconds to 99 minutes	1second	0.01 %	BP 2007/Disintegration/ Disintegration tester
Bexus 750 Tablets	Quantitative Analysis	0.206 – 22.1 µg/ml	0.068 µg/ml	0.02%	In house /Spectrophotometry/Spec trophotometer
	Weighing	1 mg to 200 g	0.1 mg	0.01 %	USP/Weighing of material/Analytical balance
	Friability	0.05 %- 5 %	0.01%	0.01 %	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test	30 seconds to 99 minutes	1second	0.01 %	BP 2007/Disintegration/ Disintegration tester
Bexus 250 Infusion	Quantitative Analysis	0.206 – 22.1 µg/ml	0.068 µg/ml	0.02%	In house /Spectrophotometry/Spec trophotometer
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Bexus 500 Infusion	Quantitative Analysis	0.206 – 22.1 µg/ml	0.068 µg/ml	0.02%	In house /Spectrophotometry/Spec trophotometer

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Bexus 500 Infusion	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Bexus 750 Infusion	Quantitative Analysis	0.206 – 22.1 µg/ml	0.068 µg/ml	0.02%	In house /Spectrophotometry/Spec trophotometer
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Clozox T- Cream	Quantitative Analysis	2.64 – 50 µg/ml	0.873µg/ml	0.02%	BP 2007/Chromatography/H PLC
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Clozox 0.1g Tablets	Quantitative Analysis	2.64 – 50 µg/ml	0.873µg/ml	0.02%	BP 2007/Chromatography/H PLC
	Weighing	1 mg to 200 g	0.1 mg	0.01%	USP2007/Weighing of material/Analytical balance
	Friability	0.05 %- 5 %	0.01%	0.01%	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test	30 seconds to 99 minutes	1second	0.01%	BP 2007/Disintegration/ Disintegration tester
Clozox 0.5g Tablets	Quantitative Analysis	2.64 – 50 µg/ml	0.873µg/ml	0.02%	BP 2007/Chromatography/H PLC
	Weighing	1 mg to 200 g	0.1 mg	0.01%	USP/Weighing of material/Analytical balance
	Friability	0.05 %- 5 %	0.01%	0.01%	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test	30 seconds to 99 minutes	1second	0.01%	BP 2007/Disintegration/ Disintegration tester
Clozox V- Cream	Quantitative Analysis	2.64 – 50 µg/ml	0.873µg/ml	0.02%	BP 2007/Chromatography/H PLC
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Clycin V Cream	Quantitative Analysis	39.83 – 500 µg/ml	13.14 µg/ml	0.02%	USP 2007/Chromatography/H PLC
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Clycin T Lotion	Quantitative Analysis	39.83 – 500 µg/ml	13.14 µg/ml	0.02%	USP 2007/Chromatography/H PLC

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Clycin T Lotion	pH		2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Famot 20 Tablets	Quantitative Analysis		0.571 – 63.5 µg/ml	0.188 µg/ml	0.02%	BP 2007 /Spectrophotometry/Spec trophotometer
	Weighing		1 mg to 200 g	0.1 mg	0.01%	USP/Weighing of material/Analytical balance
	Friability		0.05 %- 5 %	0.01%	0.01%	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test		30 seconds to 99 minutes	1second	0.01%	BP 2007/Disintegration/ Disintegration tester
Famot 40 Tablets	Quantitative Analysis		0.571 – 63.5 µg/ml	0.188 µg/ml	0.02%	BP 2007 /Spectrophotometry/Spec trophotometer
	Weighing		1 mg to 200 g	0.1 mg	0.01%	USP/Weighing of material/Analytical balance
	Friability		0.05 %- 5 %	0.01%	0.01%	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test		30 seconds to 99 minutes	1second	0.01%	BP 2007/Disintegration/ Disintegration tester
Fudic Cream	Quantitative Analysis		1.564 – 50 µg/ml	0.516 µg/ml	0.02%	In House /Chromatography/HPLC
	pH		2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Melofin Tablets	Quantitative Analysis	Sulfadoxine	47.685 – 400.8 µg/ml	15.73 µg/ml	0.02%	In House /Chromatography/HPLC
		Pyrimethamine	1.41 – 50 µg/ml	0.465 µg/ml	0.02%	
	Weighing		1 mg to 200 g	0.1 mg	0.01%	USP/Weighing of material/Analytical balance
	Friability		0.05 %- 5 %	0.01%	0.01%	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test		30 seconds to 99 minutes	1second	0.01%	BP 2007/Disintegration/ Disintegration tester
Melofin Suspension	Quantitative Analysis	Sulfadoxine	47.685– 400.8 µg/ml	15.73 µg/ml	0.02%	In House/Chromatography/ HPLC
		Pyrimethamine	1.41– 50 µg/ml	0.465 µg/ml	0.02%	
	pH		2-12	0.01	0.07	BP 2007 /pH determination/ pH meter

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Warfin Tablets	Quantitative Analysis	1.113– 46.4 µg/ml	0.367 µg/ml	0.02%	BP 2007 /Spectrophotometry/Spec trophotometer
	Weighing	1 mg to 200 g	0.1 mg	0.01%	USP/Weighing of material/Analytical balance
	Friability	0.05 %- 5 %	0.01%	0.01%	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test	30 seconds to 99 minutes	1second	0.01%	BP 2007/Disintegration/ Disintegration tester
Zepar Suspension	Quantitative Analysis	0.751– 31.8 µg/ml	0.248µg/ml	0.02 %	UV-VISIBLE (USP 2000)
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
Zepar Tablets	Quantitative Analysis	0.751– 31.8 µg/ml	0.248µg/ml	0.02 %	UV-VISIBLE (USP 2000)
	Weighing	1 mg to 200 g	0.1 mg	0.01%	USP/Weighing of material/Analytical balance
	Friability	0.05 %- 5 %	0.01%	0.01%	BP 2007/Friability of uncoated tablet/Friabilator
	Disintegration test	30 seconds to 99 minutes	1second	0.01%	BP 2007/Disintegration/ Disintegration tester
Water For Injection	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
	Conductivity	0.1-1999µs	0.1 µs	0.02%	USP2007 /Conductivity / Conductivity meter
Albendazole	Quantitative analysis	0.751– 31.8 µg/ml	0.248µg/ml	0.02 %	USP2007 /Spectrophotometry/Spec trophotometer
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR
	Water content	0.1% - 100%	0.01%	0.01%	USP2007 /Karl Fisher Titration / Karl Fisher Titrator
Clindamycin Phosphate	Quantitative analysis	39.83– 500 µ g/ml	13.14 µg/ml	0.02%	USP2007/Chromatograp hy/HPLC
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
	Water content	0.1% - 100%	0.01%	0.01%	USP2007 /Karl Fisher Titration / Karl Fisher Titrator

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Clotrimazole	Quantitative analysis	2.64 – 50 µ g/ml	0.873µg/ml	0.02%	BP 2007/Chromatography/H PLC
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR
Famotidine	Quantitative analysis	0.571– 63.5 µ g/ml	0.188 µg/ml	0.02%	BP 2007/Spectrophotometry/ Spectrophotometer
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR
	Water content	0.1% - 100%	0.01%	0.01%	USP2007 /Karl Fisher Titration / Karl Fisher Titrator
Fusidic Acid	Quantitative analysis	1.564– 50 µ g/ml	0.516 µg/ml	0.02%	HPLC (In House)
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR
	Water content	0.1% - 100%	0.01%	0.01%	USP2007 /Karl Fisher Titration / Karl Fisher Titrator
Levofloxacin hemi hydrate	Quantitative analysis	0.206– 22.1 µ g/ml	0.068 µg/ml	0.02%	In house /Spectrophotometry/Spec trophotometer
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR
	Water content	0.1% - 100%	0.01%	0.01%	USP2007 /Karl Fisher Titration / Karl Fisher Titrator
Pefloxacin Mesylate	Quantitative analysis	0.354– 21 µg/ml	0.117 µg/ml	0.02%	In house /Spectrophotometry/Spec trophotometer
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
	Water content	0.1% - 100%	0.01%	0.01%	USP2007 /Karl Fisher Titration / Karl Fisher Titrator
Pyrimethamine	Quantitative analysis	1.41– 50 µg/ml	0.465 µg/ml	0.02%	In House/Chromatography/ HPLC
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR

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Warfarin	Quantitative analysis	1.113– 46.4 µg/ml	0.367 µg/ml	0.02%	BP 2007 /Spectrophotometry/Spec trophotometer
	Identification	600 Cm ⁻¹ – 4000 Cm ⁻¹	600 cm ⁻¹	0.01%	BP 2007 /Infrared/ FTIR
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter
	Water content	0.1% - 100%	0.01%	0.01%	USP2007 /Karl Fisher Titration / Karl Fisher Titrator
Water	Conductivity	0.1-1999µs	0.1 µs	0.02%	USP2007 /Conductivity / Conductivity meter
	pH	2-12	0.01	0.07	BP 2007 /pH determination/ pH meter

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