



ACCREDITATION DOCUMENT

F-06/02
Issue Date: 26/05/08
Rev. No: 05
LAB 004

Testing Laboratory.

Accreditation Scope of Platinum Pharmaceuticals (Pvt) Ltd. Karachi, Pakistan

Permanent laboratory premises

Materials/ Products tested	Type of Tests/ Properties measurement	Rang of Measurement	Minimum Detection Limit	Uncertainty of Measurement (where applicable) MU (±)	Standard Specification/ Techniques/ Equipment used
Brethin Tablets 2.5 mg	Assay	90% - 110 % of label claim	0.24 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	75 % - 110 %	0.003 mg / ml	2 %	USP: Physical Tests (711) Dissolution / (Apparatus: I (Basket)
	Disintegration	0.5 min - 15 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	USP / Liquid chromatography / HPLC
	Uniformity of weight	190 mg – 210 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Brethin Tablets 5 mg	Assay	90% - 110% of label claim	0.24 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	75 % - 110%	0.003 mg / ml	2 %	USP: Physical Tests (711) Dissolution / (Apparatus: I (Basket)
	Disintegration	0.5 min - 15 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	USP / Liquid chromatography / HPLC
	Uniformity of weight	380 mg – 420 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Cabok Tablets 10 mg	Assay	90% - 110% of label claim	0.08 mg / ml	2 %	Internal / Liquid chromatography / HPLC
	Dissolution	75 % - 110%	0.006 mg / ml	2 %	BP: Appendix XII D. Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms) / Apparatus: II (Paddle)
	Disintegration	0.5 min - 15 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus

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Cabok Tablets 10 mg	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	380 mg – 420 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Cabok Tablets 5 mg	Assay	90% -110% of label claim	0.08 mg / ml	2 %	Internal / liquid chromatography / HPLC
	Dissolution	75 % - 110%	0.006 mg / ml	2 %	BP: Appendix XII D. Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms) / Apparatus: II (Paddle)
	Disintegration	0.50 min - 15 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	190 mg – 210 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Cardaxen Tablets 100 mg	Assay	92.5-107.5% of label claim	0.08 mg / ml	2 %	BP / UV absorbance / UV Vis. Spectrophotometer
	Disintegration	0.50 min – 30 min	0.25 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP Test B: Appendix II B. Ultraviolet and visible absorption spectrophotometry / UV /Vis. Spectrophotometer
	Uniformity of weight	394 mg – 436 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Cardaxen Tablets 25 mg	Assay	92.5-107.5% of label claim	0.08 mg / ml	2 %	BP / UV absorbance / UV Vis. Spectrophotometer
	Disintegration	0.50 min - 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP Test B: Appendix II B. Ultraviolet and visible absorption spectrophotometry / UV /Vis. Spectrophotometer

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Cardaxen Tablets 25 mg	Uniformity of weight	209 mg – 231 mg	187 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Cardaxen Tablets 50 mg	Assay	92.5-107.5% of label claim	0.08 mg / ml	2 %	BP / UV absorbance / UV Vis. Spectrophotometer
	Disintegration	0.50 min - 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP Test B: Appendix II B. Ultraviolet and visible absorption spectrophotometry / UV /Vis. Spectrophotometer
	Uniformity of weight	198 mg – 219 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Cedrox Tablets 1 g	Assay	90-120% of label claim	0.40 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	75% - 100%	0.018 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: II (Paddle)
	Disintegration	0.50 min - 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	/ Water contents	0.1 % - 8.0 %	0.0001 %	0.01 %	USP/ USP: Physical Tests (921) Water Determination: Method 1a / Karl Fischer Titrator
	Uniformity of weight	1197 mg – 1323 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Ceftas Suspension 100 mg / 5 ml	Assay	90-120% of label claim	0.128 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Deliverable volume	30 ml	10 ml	0.5 ml	USP: Physical Tests (698) Deliverable volume / Measuring Cylinder
	Identification Test	Qualitative	Qualitative	Not applicable	USP / Liquid chromatography / HPLC
	pH	2.5 – 4.5	0.01	0.05	USP/ USP: Physical Tests (791) pH / pH Meter
	Water contents	0.01 % - 2.0 %	0.0001 %	2 %	USP/ USP: Physical Tests (921)

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					Water Determination: Method 1a / Karl Fischer Titrator
Cedrox capsules 500 mg	Assay	90-120% of label claim	0.40 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.01 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: I (Basket)
	Disintegration	0.50 min - 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Water contents	0.01 % - 7.0 %	0.0001 %	2 %	USP/ USP: Physical Tests (921) Water Determination: Method 1a / Karl Fischer Titrator
	Uniformity of weight	556 mg – 615 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Cedrox Suspension 125 mg / 5 ml	Assay	90-120% of label claim	0.40 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Deliverable volume	60 ml	10 ml	0.5 ml	USP: Physical Tests (698) Deliverable volume / Measuring Cylinder
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	pH	4.5 – 6.0	0.01	0.05	USP/ USP: Physical Tests (791) pH / pH Meter
	Water contents	0.01 % - 2 %	0.0001 %	0.01 %	USP/ USP: Physical Tests (921) Water Determination: Method 1a / Karl Fischer Titrator
Cedrox Suspension 250 mg / 5 ml	Assay	90-120% of label claim	0.40 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Deliverable volume	60 ml	10 ml	0.5 ml	USP: Physical Tests (698) Deliverable volume / Measuring Cylinder
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	pH	4.5 – 6.0	0.01	0.05	USP/ USP: Physical Tests (791) pH / pH Meter

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	Water contents	0.01 % - 2.0 %	0.0001 %	0.01 %	USP/ USP: Physical Tests (921) Water Determination: Method 1a / Karl Fischer Titrator
Digox Tablet 250 mcg	Assay	90-110% of label claim	0.032 mg / ml	2 %	BP / UV Absorbance / UV-Vis. Spectrophotometer
	Disintegration	0.50 min - 15 min	100 mg	2 %	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Uniformity of weight	133 mg – 147 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Dolonap Tablets 250 mg	Assay	95-105% of label claim	0.04 mg / ml	2 %	BP / UV Absorbance / UV-Vis. Spectrophotometer
	Dissolution	75 % - 110 %	0.016 mg / ml	2 %	BP: Appendix XII D. Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms) / Apparatus: II (Paddle)
	Disintegration	0.50 min - 15 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP Test B: Appendix II B. Ultraviolet and visible absorption spectrophotometry / UV /Vis. Spectrophotometer
	Uniformity of weight	364 mg – 402 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Dolonap Tablets 500 mg	Assay	95-105% of label claim	0.04 mg / ml	2 %	BP / UV Absorbance / UV-Vis. Spectrophotometer
	Dissolution	75 % - 110 %	0.03 mg / ml	2 %	BP: Appendix XII D. Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms) / Apparatus: II (Paddle)
	Disintegration	0.50 min - 15 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP Test B: Appendix II B. Ultraviolet and visible absorption spectrophotometry / UV /Vis. Spectrophotometer
	Uniformity of weight	729 mg – 805 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance

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Emiset Tablets 10 mg	Assay	95-105% of label claim	0.10 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Dissolution	75 % - 110 %	0.006 mg / ml	2 %	BP: Appendix XII D. Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms) / Apparatus: II (Paddle)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP Test B / HPLC
	Uniformity of weight	144 mg – 160 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Fastaid Tablets 25 mg	Assay	95 % -105 % of label claim	0.04 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Disintegration	0.25 min – 30 min	0.25 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	198 mg - 220 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Fastaid Tablets 50 mg	Assay	95 % - 105% of label claim	0.04 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	199 mg – 221 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Fastaid Tablets 75 mg	Assay	95-105% of label claim	0.04 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Disintegration	0.25 min – 30 min	0.25 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	228 mg – 252 mg	100 mg	2 %	BP Appendix XII G. Uniformity of

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					Weight (Mass) / Analytical Balance
Fastaid Tablets SR 100 mg	Assay	95-105% of label claim	0.04 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	241 mg – 267 mg	100 mg	2 %	BP: Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Nordox Capsules 100 mg	Assay	90% - 120% of label claim	0.016 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.006 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: II Paddle)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Water contents	0.01 % - 8.5 %	0.0001 %	2 %	USP/ USP: Physical Tests (921) Water Determination: Method 1a / Karl Fischer Titrator
Uniformity of weight	285 mg – 315 mg	100 mg	2 %	BP: Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance	
Novelink Capsules 500 mg	Assay	90-120% of label claim	0.96 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Water contents	0.01 % - 7.0 %	0.0001 %	2 %	USP/ USP: Physical Tests (921) Water Determination: Method 1a / Karl Fischer Titrator
	Uniformity of weight	564 mg – 624 mg	100 mg	2 %	BP: Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Noxalam Tablets 0.5 mg	Assay	90-110% of label claim	0.08 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.03 mg / ml	2 %	USP: Physical Tests (711)

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Materials/ Products tested	Type of Tests/ Properties measurement	Rang of Measurement	Minimum Detection Limit	Uncertainty of Measurement (where applicable) MU (±)	Standard Specification/ Techniques/ Equipment used
					Dissolution / Apparatus: II Paddle)
Noxalam Tablets 0.5 mg	Disintegration	0.50 min – 15 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	133 mg – 147 mg	100 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical Balance
Prodent Mouthwash	Assay	90 % - 110% of label claim	0.08 mg / ml	2 %	Internal / Liquid chromatography / HPLC
	Deliverable volume	150 ml and 300 ml	20 ml and 50 ml	1.5 mg and 2.5 mg	BP: Appendix XII M. Test for Deliverable Weight (Mass) or Volume of Liquid and Semi-solid Preparations / Measuring Cylinder
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	pH	5.5 – 6.5	0.01	0.05	Internal / BP: Appendix V L. Determination of pH values / pH Meter
Prozyn Capsules 20 mg	Assay	90-110% of label claim	0.16 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.012 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: II Paddle)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	192 mg – 213 mg	100 mg	2 %	USP / HPLC
Reducid Tablets 10 mg	Assay	90-110% of label claim	0.08 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	75 % - 110 %	0.012 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: II Paddle)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	/ USP Test B / Liquid

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Materials/ Products tested	Type of Tests/ Properties measurement	Rang of Measurement	Minimum Detection Limit	Uncertainty of Measurement (where applicable) MU (\pm)	Standard Specification/ Techniques/ Equipment used
					chromatography / HPLC
Reducid Tablets 10 mg	Uniformity of weight	197 mg – 218 mg	176 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass)
Reducid Tablets 20 mg	Assay	90% - 110% of label claim	0.08 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	75 % - 110 %	0.012 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: II (Paddle)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	/ USP Test B / Liquid chromatography / HPLC
	Uniformity of weight	197 mg – 218 mg	176 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / Analytical balance
Reducid Tablets 40 mg	Assay	90-110% of label claim	0.08 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	75 % - 110 %	0.012 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: II (Paddle)
	Disintegration	0.25 min – 30 min	0.25 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	/ USP Test B / Liquid chromatography / HPLC
	Uniformity of weight	197 mg – 218 mg	176 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) Analytical balance
Renata Tablets 150 mg	Assay	90%-110% of label claim	0.012 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.009 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: II (Paddle)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	/ USP Test B / Liquid chromatography / HPLC

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	Uniformity of weight	408 mg – 452 mg	387 mg	2 %	BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Renata Tablets 75 mg	Assay	90 %-110 % of label claim	0.012 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.009 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: II (Paddle)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	/ USP Test B / Liquid chromatography / HPLC
	Uniformity of weight	204 mg – 226 mg	100 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Seizunil Tablets 200 mg	Assay	95-105% of label claim	0.24 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	285 mg – 315 mg	100 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Seizunil Tablets 400 mg	Assay	95-105% of label claim	0.24 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Disintegration	0.25 min – 30 min	0.25 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Uniformity of weight	668 mg – 739 mg	633 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Solvecef Capsules 500 mg	Assay	90-120% of label claim	0.80 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.012 mg / ml	2 %	USP: Physical Tests (711) Dissolution / Apparatus: I (Basket)

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	Disintegration	0.25 min – 30 min	0.25 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration /Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Water contents	0.01 % - 10.0 %	0.0001 %	2 %	USP/ USP: Physical Tests (921) Water Determination: Method 1a / Karl Fischer Titrator
	Uniformity of weight	551 mg – 609 mg	100 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Suprox Tablets 250 mg	Assay	90% -110% of label claim	0.16 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.003 mg / ml	2 %	USP: Physical Tests (711) Dissolution / (Apparatus: II (Paddle)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	USP Test A / Liquid chromatography / HPLC
	Uniformity of weight	380 mg – 420 mg	360 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Suprox Tablets 500 mg	Assay	90% -110% of label claim	0.16 mg / ml	2 %	USP / Liquid chromatography / HPLC
	Dissolution	80 % - 110 %	0.003 mg / ml	2 %	USP / USP: Physical Tests (711) Dissolution / (Apparatus: II (Paddle)
	Disintegration	0.25 min – 30 min	0.25 min	0.25 min	USP / USP: Physical Tests: (701) Disintegration / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	USP Test A / Liquid chromatography / HPLC
	Uniformity of weight	766 % - 848 %	100 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Synalgo Tablets 100 mg	Assay	92.5-107.5% of label claim	0.004 mg / ml	2 %	BP / UV absorbance / UV Vis. Spectrophotometer
	Disintegration	0.25 min – 30 min	0.25 min	0.25 min	BP / BP: Appendix XII A.

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Materials/ Products tested	Type of Tests/ Properties measurement	Rang of Measurement	Minimum Detection Limit	Uncertainty of Measurement (where applicable) MU (±)	Standard Specification/ Techniques/ Equipment used
					Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Uniformity of weight	389 mg – 431 mg	369 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Thyro tablets 50 mcg	Assay	90-110% of label claim	0.032 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Uniformity of weight	133 mg – 147 mg	100 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Velora Capsules 250 mg	Assay	90-105% of label claim	0.40 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Dissolution	75 % - 110 %	0.008 mg / ml	2 %	BP: Appendix XII D. Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms) / Apparatus I (Basket)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Loss on drying	0.01 % - 7.0 %	0.001 %	0.01	BP: Appendix IX D. Determination of Loss on Drying / Moisture Balance
	Uniformity of weight	280 mg – 310 mg	236 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Velora Capsules 500 mg	Assay	90 % -105% of label claim	0.40 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Dissolution	75 % - 110 %	0.018 mg / ml	2 %	BP: Appendix XII D. Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms) / Apparatus I (Basket)
	Disintegration	0.50 min – 30 min	0.10 min	0.25 min	BP / BP: Appendix XII A. Disintegration Test for Tablets and Capsules / Disintegration Apparatus

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Materials/ Products tested	Type of Tests/ Properties measurement	Rang of Measurement	Minimum Detection Limit	Uncertainty of Measurement (where applicable) MU (±)	Standard Specification/ Techniques/ Equipment used
	Identification Test	Qualitative	Qualitative	Not applicable	Internal / Liquid chromatography / HPLC
	Loss on drying	0.01 % - 7.0 %	0.001 %	0.01 %	BP: Appendix IX D. Determination of Loss on Drying / Moisture Balance
	Uniformity of weight	560 mg – 620 mg	100 mg	2 %	BP / BP Appendix XII G. Uniformity of Weight (Mass) / analytical balance
Velora Dry Suspension 125 mg / 5 ml	Assay	90%-110% of label claim	0.40 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Deliverable volume	60 ml	10 ml	10 ml	BP: Appendix XII M. Test for Deliverable Weight (Mass) or Volume of Liquid and Semi-solid Preparations / Measuring Cylinder
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP Test A: Appendix II B. Ultraviolet and visible absorption spectrophotometry / UV /Vis. Spectrophotometer
	pH	3.5 – 6.0	0.01	0.05	BP/ BP: Appendix V L. Determination of pH values / pH Meter
Velora Dry Suspension 250 mg / 5 ml	Assay	90% -110% of label claim	0.40 mg / ml	2 %	BP / Liquid chromatography / HPLC
	Deliverable volume	60 ml	10 ml	10 ml	BP: Appendix XII M. Test for Deliverable Weight (Mass) or Volume of Liquid and Semi-solid Preparations / Measuring Cylinder
	Identification Test	Qualitative	Qualitative	Not applicable	BP / BP Test A: Appendix II B. Ultraviolet and visible absorption spectrophotometry / UV /Vis. Spectrophotometer
	pH	3.5 – 6.0	0.01	0.05	BP BP: Appendix V L. Determination of pH values / pH Meter

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