

## CONTENTS

<b>1.</b>	<b>EXECUTIVE SUMMARY</b> .....
<b>2</b>	<b>OBSERVATIONS (O), RECOMMENDATIONS (R) AND RESPONSES (RESP)</b> .....
2.1	Critical Observations.....
2.2	Major Observations.....
2.3	Other Observations.....
2.4	Other (Non-GMP) Observations.....
<b>3.</b>	<b>AUDIT ORGANISATION</b> .....
3.1	Contact Information.....
3.2	Audit Standard.....
3.3	Purpose.....
3.4	Scope.....
3.5	Areas Reviewed.....
3.6	Classification of Observations.....
3.7	Auditors.....
3.8	Audit Hosts.....
3.9	Conventions and Abbreviations.....
<b>4.</b>	<b>COMPANY INFORMATION</b> .....
4.1	Orientation.....
4.2	Accreditation.....
4.3	Regulatory Inspection.....
<b>5.</b>	<b>QUALITY MANAGEMENT</b> .....
5.1	Quality Assurance.....
<b>6.</b>	<b>QUALITY SYSTEMS</b> .....
6.1	Principle Controls.....
6.1.1	Change Control.....
6.1.2	Document Control.....
6.1.3	Records.....
6.1.4	Corrective and Preventative Actions.....
6.1.5	Internal Audit.....
6.1.6	Customer Complaints.....
6.1.7	Control of Non-Conforming Product.....
6.1.8	Purchasing and Supplier Control.....
6.1.9	Validation.....
6.1.10	Calibration.....
6.1.11	Preventative Maintenance.....
6.1.12	Cleaning Validation and Cleaning.....
6.1.13	Training.....
6.1.14	Business Continuity Planning.....
<b>7.</b>	<b>COMPUTERISED SYSTEMS</b> .....
7.1	Office Systems.....
7.2	Factory Systems.....
7.3	Laboratory Systems.....
<b>8.</b>	<b>QUALITY CONTROL</b> .....
8.1	Analytical Laboratories.....
8.1.1	Equipment.....
8.1.2	Raw Materials Testing.....
8.1.3	In-Process Testing.....
8.1.4	Finished Product Testing.....
8.1.5	Stability Testing.....

8.2	Product Development Laboratories.....
<b>9.</b>	<b>BUILDINGS AND FACILITIES.....</b>
9.1	Buildings.....
9.1.1	Construction.....
9.1.2	Equipment.....
9.1.3	Security.....
9.1.4	Fire Safety.....
9.1.5	Hazardous Chemicals.....
9.2	Utilities.....
9.2.1	Potable Water.....
9.2.2	Purified Water.....
9.2.3	Heating Systems.....
9.2.4	Chilled and Cooled Water Systems.....
9.2.5	Gases.....
9.2.6	Electricity.....
9.3	Environmental Control.....
9.3.1	Pest Control.....
9.3.2	Hygiene.....
9.3.3	Cleaning.....
9.3.4	Protective Clothing.....
9.3.5	Waste Management, Aerial and Liquid Discharges.....
<b>10.</b>	<b>REVIEW OF THE MANUFACTURING PROCESS.....</b>
10.1	Kurkumbh Site D-7.....
10.1.1	Process Flow Diagrams.....
10.1.2	GMP Introduction Points.....
10.1.3	Raw Materials Receipt and Dispensing.....
10.1.4	Materials Charging, Reaction and Isolation, BD I and BD II.....
10.1.5	Bulk Drugs Finishing BD I and BD II.....
10.1.6	Materials Charging, Reaction and Isolation, BD III - V.....
10.1.7	Finishing BD III - V.....
10.1.8	Quality Control.....
10.1.9	Finished Goods Warehouse and Despatch.....
10.1.10	Annual Product Reviews, Deviations and Complaints.....
10.2	Kurkumbh Site D-22.....
10.2.1	Process Flow Diagram.....
10.2.2	GMP Introduction Points.....
10.2.3	Raw Materials Receipt and Dispensing.....
10.2.4	Production Processing.....
10.2.5	Quality Control.....
10.2.6	Annual Product Reviews.....
<b>11.</b>	<b>APPENDICES.....</b>
	APPENDIX 1 AUDITORS' CVS.....
	APPENDIX 2 SITE PLAN KURKUMBH PLANT D7.....
	APPENDIX 3 SITE PLAN KURKUMBH PLANT D22.....
	APPENDIX 4 PRODUCT LIST.....
	APPENDIX 5 EN ISO 14001 CERTIFICATE.....
	APPENDIX 6 BRITISH SAFETY COUNCIL 5-STAR CERTIFICATE.....
	APPENDIX 7 RENEWAL OF LICENCES.....
	APPENDIX 8 QUALITY STATEMENT.....
	APPENDIX 9 COMPANY ORGANOGRAM.....
	APPENDIX 10 DEVIATION CONTROL FLOW CHART.....
	APPENDIX 11 INTERNAL AUDIT PROGRAMME, 2006 - D7.....
	APPENDIX 12 INTERNAL AUDIT PROGRAMME, 2006 - D22.....
	APPENDIX 13 COMPLAINT CONTROL FLOW CHART.....
	APPENDIX 14 TRAINING PROGRAMME, 2006 - D7.....
	APPENDIX 15 TRAINING PROGRAMME, 2006 - D22.....

APPENDIX 16	LIST OF ANALYTICAL AND TESTING EQUIPMENT, QC LABORATORY, D7.....
APPENDIX 17	LIST OF ANALYTICAL AND TESTING EQUIPMENT, QC LABORATORY, D22.....
APPENDIX 18	LIST OF MAJOR EQUIPMENT, BULK DRUGS I D7.....
APPENDIX 19	LIST OF MAJOR EQUIPMENT, BULK DRUGS II, D7.....
APPENDIX 20	LIST OF MAJOR EQUIPMENT, BULK DRUGS III, D7.....
APPENDIX 21	LIST OF MAJOR EQUIPMENT, BULK DRUGS IV, D7.....
APPENDIX 22	LIST OF MAJOR EQUIPMENT, BULK DRUGS V, D7.....
APPENDIX 23	LIST OF MAJOR EQUIPMENT, BULK DRUGS FINISHING AREA, D7.....
APPENDIX 24	LIST OF MAJOR EQUIPMENT, BULK DRUGS I, D22.....
APPENDIX 25	LIST OF MAJOR EQUIPMENT, BULK DRUGS II, D22.....
APPENDIX 26	LIST OF MAJOR EQUIPMENT, BULK DRUGS III, D22.....
APPENDIX 27	LIST OF MAJOR EQUIPMENT, BULK DRUGS FINISHING AREA, D22.....
APPENDIX 28	PURIFIED WATER SYSTEM DIAGRAM AND LIST OF SAMPLING POINTS D-7.....
APPENDIX 29	PURIFIED WATER SYSTEM DIAGRAM AND LIST OF SAMPLING POINTS D-22.....
APPENDIX 30	AQUEOUS EFFLUENT TREATMENT.....
APPENDIX 31	ORGANIC EFFLUENT TREATMENT.....
APPENDIX 32	MATERIALS FLOW RAW MATERIALS WAREHOUSE D-7.....