

GREEN FIELD PROJECT DOCUMENTS LIST

S. No	Documents Title
1.	New Facility URS
2.	SOP on SOP
3.	Documents Control Procedure SOP
4.	Equipment Qualification SOP
5.	Facility Designing and Qualification SOP
6.	Allotment of Numbering system SOP
7.	Training Program SOP
8.	Good Documentation's Practices SOP
9.	Change Control Procedures SOP
10.	Handling of Deviation SOP
11.	Handling OF CAPA
12.	Quality Risk Management
13.	Root Cause Analysis tool
14.	URS of HVAC system
15.	AHU DQ protocol and Report
16.	FAT & SAT protocol cum report
17.	AHU IQ protocol and Report
18.	AHU OQ protocol and Report
19.	AHU PQ protocol and Report



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S. No	Documents Title
20.	HVAC System Handling and operation SOP
21.	URS of water System
22.	Water system FAT/SAT Protocol
23.	Water system DQ, IQ, OQ, PQ protocol and Report
24.	Water system handling & Operation SOP
25.	SOP of Site Master File
26.	Site Master File
27.	SOP of Validation Master Plan
28.	Utility Qualification Planner
29.	Computer Validation Planner
30.	Equipments Qualification Planner
31.	Risk Assessment SOP
32.	Facility Risk Assessment
33.	DQ , IQ documents for Facility & Utility
34.	Room Data Sheets
35.	URS and Qualification documents for Compressed Air & air drier
36.	URS and Qualification documents for BMS system
37.	URS and Qualification documents for Boiler
38.	URS and Qualification documentsfor fire Hydrant
39.	URS and Qualification documentsfor Smoke detection system
40.	URS for earthing system



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S. No	Documents Title
41.	URS and Qualification documentsfor Trnsformer
42.	URS and Qualification documents for DG
43.	URS for LIFT
44.	URS and Qualification documents for chiller unit
45.	URS and Qualification documentsfor cooling Tower
46.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Autocoater
47.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOPfor Roller Compector
48.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP Shifter
49.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for RMG
50.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Paste Kettle
51.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for FBD
52.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Multimill
53.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Octagonal Blender
54.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Lifter
55.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Compression Machine
56.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and for URS for Deduster cum metal detector
57.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for auto coater Machine
58.	URS , DQ, FAT/ SAT , IQ, OQ , PQ and SOP for colloidal Mill
59.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for dispensing booth RLAF
60.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Sampling booth RLAF





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S. No	Documents Title
61.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for visual inspection machine
62.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Dynamic Passbox
63.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Static Pasbox
64.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Weighing Balance
65.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Blister Machine
66.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for Strip Machine
67.	URS, DQ, FAT/ SAT , IQ, OQ , PQ and SOP for ALU - ALU Machine
68.	QC Instruments URS and Qualification Documents
69.	URS and Qualification documents of Stability Chamber
70.	URS and Qualification documents of Disintegration Test Apparatus
71.	URS and Qualification documents of Tablet Friability Tester
72.	URS and Qualification documents of HPLC
73.	URS and Qualification documents of UV
74.	URS and Qualification documents of FTIR
75.	URS and Qualification documents of Disintegration Test Apparatus
76.	URS and Qualification documents of Dissolution test Apparatus
77.	URS and Qualification documents of Photo stability Chamber
78.	URS and Qualification documents of Analytical Balance
79.	URS and Qualification documents of Moisture Analyzer
80.	URS and Qualification documents of SS Standard Weight Set
81.	URS and Qualification documents of Sampling Rod Powder





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S. No	Documents Title
82.	URS and Qualification documents of PH Meter
83.	URS and Qualification documents Leak Test Apparatus
84.	URS and Qualification documents of BOD Incubator
85.	URS and Qualification documents of Cooling Cabinet
86.	URS and Qualification documents of Conductivity Meter
87.	URS and Qualification documents of Colony Counter
88.	URS and Qualification documents of Viscometer
89.	URS and Qualification documents of Digimatic Caliper
90.	URS and Qualification documents of Bio Safety Cabinet
91.	URS and Qualification documents of Microscope
92.	URS and Qualification documents of Fume Hood
93.	URS and Qualification documents of Gas Chromatography
94.	URS and Qualification documents of Air Sampler
95.	URS and Qualification documents of Karl Fischer Potentiometer
96.	URS and Qualification documents of Polarimeter
97.	URS and Qualification documents of Tape Density Apparatus
98.	URS and Qualification documents of Refractometer
99.	URS and Qualification documents of Centrifuge with cooling
100.	URS and Qualification documents of Micro Balance
101.	All Departments SOP's SOP as per facility need Like : QA, QC , IT, ENG, HR , EHS and Production.





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S. No	Documents Title
102.	SOP for all the machine
103.	Equipment's Qualification Protocol and Report
104.	Process Validation Protocol and Report.
105.	Hold Time Study protocol and Report
106.	Uncleaned and Clean Equipment's Protocol and report
107.	Performance and validation activity for Utility, Machine and process.
108.	Quality Manual
109.	Facility Manual and Other miscellaneous Documents

