



PV (PROCESS VALIDATION) - Index

(Sample Document will provide on request)



PV Protocol

INDEX

S. NO.	CONTENTS	PAGE NO
i	Approval page	3
1	Purpose of the protocol	4
1.	Introduction	4
1.1	Objective	4
1.2	Scope	4
1.3	Reason for Concurrent Process Validation	4
1.4	Responsibilities	5
1.5	Reference documents	5
2	Description of process	6
2.1	Composition	6
2.2	Process flow diagram	7
3	Cleanliness zone requirements	8
4	Special precautionary measures	8
5	Evaluation of critical process parameters	9
6	Sampling plan and Acceptance criteria	10



**PV- report
Index**

S. NO.	CONTENTS	PAGE NO
i	Approval page	3
1	Purpose of Report	4
2	Summary of validation activities	4
3	Deviations to Protocol	4
4	Description of Process, equipment and testing performed	4
5	Results and discussions	4
6	Additional Testing and deviations	4
7	Conclusions	5