

Appendix 5

Check List for Change Control Assessment

	Non Critical Materials	Critical Materials
Impact on site SOPs, batch documentation etc.	X	X
Impact on supply	X	X
Training of personnel	X	X
Process validation		X
Cleaning Validation	X	X
Equipment Qualification		X
Safety	X	X
Environmental	X	X
TSE assessment	X	X
Stability Impact and the minimum period before release		X
Impact on testing of final product		X
Extra testing for material received	X	X
Extra testing during production		X
Extra testing requirements to assess the impact of the change		X
Regulatory impact on the filed product with all appropriate agencies. <ul style="list-style-type: none"> • For new product, the filing strategy is developed in partnership with research. • For old product the filing may be needed to be updated 		X
Down stream impact on customers		X