

Appendix 1: Examples of likely Critical/ Non Critical Raw Materials

Raw Material	Critical	Non Critical
Acids		X*
API Starting Material	X	
Bases		X*
Building Block		X*
Catalysts		X
Chromatographic resins		X*
Cleaning Agents/ detergents		X*
Enzymes		X*
Excipients used in API formulations	X	
Filter Aids		X
Gasses – Process/Utility		X*
Grignard Reagents		X
Inorganic salts		X
Labels		X
Lubricants in contact with products	X	
Media		X*
Processing Aids		X
Solvents		X*
Water		X*

X* *Review criticality if used in final API Purification or isolation step.*