

Company Name

Company Logo

## Reference To Categorization And Impact Assessment Of Changes

Following are the Details of Changes but not limited to:

Brief Description of Changes	Category	Approval Should be Obtained From
<b>1.0 Process Change:</b>		
Changing the total manufacturing Process (Different synthetic Scheme)	Major	RA, QA, QC, EHS, Engg. & Production
Changing one or more non critical Raw Materials.	Minor/Major	RA, QA, QC, EHS, & Production
Changing one or more critical Raw Materials.	Major	RA, QA, QC, EHS, & Production
Changing the input ratios of raw Materials <10%	Minor	RA, QA, EHS, & Production
Changing the input ratios of raw Materials >10%	Major	RA, QA, QC, EHS, & Production
Changing the operating parameters like temperature, pressure, duration in certain operations like reflux or maintenance of reaction mixture at certain temperature/pressure etc.	Major	RA, QA, EHS, & Production
Replacing the existing equipment reactors, Pumps, Agitated Filters, Driers, Blenders, Pulverizer) with new equipment of same or different design.	Same: Minor Different: Major	1. In case of Production Equipment - RA, QA, EHS, Engg. & Production 2. In case of QC Equipment – QA, RA, and QC
Changing the building design and layout.	Major	RA, QA, EHS, Engg. & Production
Changing the pipe lines/valves(used for transferring raw materials, in process materials, intermediates, finished product and services like water, steam brine, vacuum and compressed air)	Minor or Major	RA, QA, EHS, Engg. & Production
Change in utility	Minor/Major	RA ,QA ,EHS ,Engg.& Production
Specification and testing methods of raw Materials, in process, intermediates, finished Product and stability.	Major	RA, QA, QC, & Production

	Prepared By	Checked By	Approved By
<b>Name</b>			
<b>Department</b>			
<b>Signature</b>			
<b>Date</b>			

Issued by :  
(Sign/date )

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### 2.0 Document Changes

1) System Manual	Minor	Head QA
2) SOPs		Respective Dept. HOD/Head QA
3) STPs/Specification/Method of Analysis		Related Dept. Head & QA
4) Forms		Related Dept. Head & QA

### 3.0 Other Changes

Change in Manufacturing Site	Major	QA, Engg. Production & RA
Reprocessing /Recovery Procedures	Major	RA, Production, QA & QC
Supplier of KSM	Major	QC,QA, Production & Purchase
Supplier of Non –KSM	Minor	QC,QA, Production & Purchase
Change in Primary Packing Material and Vendor	Major	QC,QA, Production & Purchase
Change in Secondary Packing Material and Vendor	Minor	QC,QA, Production & Purchase

- **RA: Regulatory Affairs (RA) approvals are required for changes to process filed in DMF. So in case if there is no submission then QA – Head is authorized to sign in place of RA.**

	Prepared By	Checked By	Approved By
<b>Name</b>			
<b>Department</b>			
<b>Signature</b>			
<b>Date</b>			

 Issued by :  
(Sign/date )

Copy No. :