

Change Control No: **A123456**

Preliminary Information			
Plant	2015 - HDL1	Reference Notifications	OOS/2018/001
CC Created On	01-08-2018	Change Type	Manjor
Change Category	Permanent Change	Brief Description of CC	Change in Shelf life for the product Omez from 24 months to 36 months.
Change Area	Manufacturing Process		

Change Object Details			
Change Object	Change in shelf life	Existing Shelf life	24 Months
Proposed Shelf life	36 Months	Stage	Compression
Product	XYZ	Batches	XYZ
Market	USA	Impacted Document No(s)	N/A

Change Proposal Details			
Details of Change			
S.No	Existing	Proposed	Justification
1			
2			

Supporting Documents		
S.No	Document Name	View
1	Investigation Report.pdf	

S.No.	Assessment	Decision
1	Is there an impact on manufacturing MPR/MFR/eMBR?	<input checked="" type="radio"/> Yes <input type="radio"/> No
2	Is there an impact on PIL/Leaflet artwork	<input type="radio"/> Yes <input checked="" type="radio"/> No
3	Is there an impact on finished product specification COA	<input type="radio"/> Yes <input checked="" type="radio"/> No
4	Is there an impact on packing MPR/MFR/ eMBR?	<input type="radio"/> Yes <input checked="" type="radio"/> No

Action Plans			
S.No	Action Plan	Resp. Person	Time in Days
1	Batch manufacturing document (MPR/MFR/eMBR) to be revised.	Prabhakar	20 Days
2	Batch packing document (MPR/MFR/eMBR/datasheet) to be revised.	Chandu Adimulam	10 Days
3	Specification to be revised.		
4	SAP Master Data to be updated.		
5	COA template of product to be updated.		
6	Training to concern personnel to be done.		
7	Artwork of packing material to be revised.		
8	Hold note of leftover material to be obtained for blocking of material.		