CADILA HEALTHCARE LIMITED			Zydus Cadila
Annexure No.	**0301-SOP-MFG-00666-01**	**Version No.**	**1.0, CURRENT**
Annexure Title	**Derivation of Force Control Limit in Compression Machine for "KN" Value**		

Product Name				**Batch No.**		
Equipment ID.						
Average weight of tablets as per BMR (mg/g)	**Avg. (mg/g)**		**Min. (mg/g)**		**Max. (mg/g)**	

Parameter	**Observed Limit**	**LHS**	**RHS**
Compaction force at Target Average Weight	Observed Target Avg. weight (mg/g)		
	Observed Avg. compaction force – 'KN' **(A)**		
Compaction force at lower average weight	Observed Lower avg. weight (mg/g)		
	Observed Min. compaction force – 'KN' **(B)**		
	Observed Max. compaction force – 'KN' **(C)**		
Compaction force at higher average weight	Observed Higher average weight (mg/g)		
	Observed Min. compaction force – 'KN' **(D)**		
	Observed Max. compaction force – 'KN' **(E)**		

Parameter	**Derived Limit**	**LHS**	**RHS**
$Derivation of main compaction force control limit (KN)	**Lower limit:** Average Compaction force at observed target Avg. weight **(A)** - up to 1 **KN**		
	Higher limit: Average Compaction force at observed target Avg. weight **(A)** + up to 1 **KN**		
@Derivation of rejection force control limit (KN)	**Lower Limit (B):** Min. value of individual compaction force observed at lower Avg. weight		
	Higher Limit (E): Max. value of individual compaction force observed at higher Avg. weight		
Done By:			
Verified By (Production):			
Verified By (IPQA): (Verify the set limit in SCADA against derived limits)			

Note: Ensure all the tablets comply to individual weight variation limit as per BMR specification.

$ *Compaction force can be changed by the operator during the compression run to maintain the desired target weight and other quality attributes of the product.*

@ *These are derived limit for each batch and fixed for complete batch run, which is set at initial batch setting stage.*