

## QMS-145 Classification of Defects in Manufacturing Operation

### 5.2 Determine the Defect Classification and AQL

DEFECT CATEGORY	APPENDIX	CLASSIFICATION OF DEFECTS			
		CRITICAL (C)	MAJOR (A)	MAJOR (MJ)	MINOR (MN)
Bulk Manufactured Tablets	2	0.01%	N/A	1%	4%
Bulk Manufactured Tablets (Coated)	2		0.04%		
Bulk Manufactured Capsules	2		N/A		
Blister Packaging of Tablets and Capsules	3				
Tubes / Syringe / Suppositories Filling of Semi-Solids and Liquids	4				
Bottle Packaging of Tablets and Capsules	5				