

Guidance Number: 074

Table 1 – Defect Classification Criteria

Impact of Defect	Critical	Major	Minor
Effect on Consumer Safety	Will cause personal injury or illness.	May cause personal injury or illness.	Will not cause personal injury or illness.
Effect on Conformance to Regulations	Fails to conform to regulations for safety, purity, efficacy, or identity.	Fails to conform to regulations on weight, count, or volume.	Fully conforms to regulations.
Effect on Use	Will render the product totally unfit for use.	May render the product difficult or unfit for use and may cause Rejection* by user (e.g., removal from package, objectionable appearance).	Will not affect usability of the product; may affect appearance.
Consumer Relations	Will offend consumers due to odor or appearance. Will very likely result in Complaints* .	May be noticed by consumer, may be an annoyance and reduce product salability. May result in complaints.	Unlikely to be noticed by consumers, and of little concern if noticed. Not likely to result in complaints.
Loss to Company	Will lose consumers and may result in losses greater than value of product. This will include productivity or yield issues related to components.	May lose consumers and may result in losses equal to or greater than value of product. This will include productivity or yield issues related to components.	Unlikely to result in loss.