

**Annexure-III**

**Classification of Findings**

Company Logo Here

**XX PHARMACEUTICALS LIMITED**

117 Adams Street, Brooklyn, NY 11201, USA

**Classification of Findings**

**Findings Classifications**

Dependent on the nature of the findings and the risk associated with any non-Assurance the following classifications should be used:

<b>Classification</b>	<b>Description of Classification</b>	<b>Action to be Taken</b>
<b>Critical</b>	Deficiencies which have a high probability of causing adverse consequences to the patient or consumer; may result in significant deviations in the safety, identity, strength or purity of the product; or are a combination of major deficiencies which indicates a critical system failure.	The auditor is to define which operations, or supply to XX Pharma, must stop until corrective and preventive actions (CAPAs) are implemented.
<b>Major</b>	Deficiencies which could potentially cause adverse consequences to the patient or consumer if left un-addressed, could be considered indicative of poor control, could be considered major deviations by regulatory authorities, or a combination of minor deficiencies which indicate a major systems failure, or a number of repetitive minor deficiencies.	CAPAs are to be agreed although operations can proceed.
<b>Minor</b>	A deficiency which cannot be classified as critical or major.	CAPAs are to be agreed although operations can proceed.
<b>Note</b>	A deficiency, which is not related to GMP or regulatory conformance requirements e.g. Environmental Health and Safety, but does warrant attention by the auditee.	CAPAs do not need to be agreed with the lead auditor.