Annexure 11

WHO Tool for Causality Assessment

INSTITUTIONAL ETHICS COMMITTEE-CHARUSAT

**CAUSALITY ASSESSMENT**

**Clinical Trial Protocol No. : Clinical Trial Title:**

**Reference**:

* CentreNumber:
* PatientID:
* SAE:
* Date:

**WHO Causality Assessment Categories**

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| --- | --- |
| **Causality Term** | **Assessment Criteria\*** |
| Certain | * Event or Laboratory Test abnormality, with plausible time relationshiptodrugintake * Cannot be explained by disease or otherdrugs * A response to withdrawal plausible (pharmacologically and/ orpathologically) * Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognizedpharmacologicalphenomenon) * Re-challenge satisfactory, ifnecessary |
| Probable/ Likely | * Event or Laboratory Test abnormality, with reasonable time relationship to drugintake * Unlikely to be attributed to disease or otherdrugs * A response to withdrawal clinicallyreasonable * Re-challenge notrequired |
| Possible | * Event or Laboratory Test abnormality, with reasonable time relationship to drugintake * Could also be explained by disease or otherdrugs * Information on drug withdrawal may be lacking orunclear |
| Unlikely | * Event or Laboratory Test abnormality, with a time to drug intake that makes a relationship improbable (but notimpossible) * Disease or other drugs provide plausibleexplanations |
| Conditional/ Unclassified | * Event or Laboratory Testabnormality * More data for proper assessment needed,or * Additional data underexamination |
| Not assessable/ Unclassifiable | * Report suggesting an adversereaction * Cannot be judged because information is insufficient orcontradictory * Data cannot be supplemented orverified |

\*All points should be reasonably compliedwith.