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**

|  |  |
| --- | --- |
| **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.