Template of Certificate of Analysis

- Reference material name:
- Batch/Lot number/Identification code:
- Reference monographs:

Tests	Specifications	Results
Description		
Identification		
Water content/ Loss on drying		
Assay± SD		
Purity (100-Total impurities%)		

- Storage conditions:
- Manufacturer name/Supplier:
- Expiry/Re-test date:
- Weight:
- Safety instructions:

Traceability Statement:

☐ This material is Traceable to : …… RS, lot no ……..

☐ This material is traceable to the standard Method (……)

☐ The calibration of measuring instruments used is traceable to standard international(SI) or certified reference material.

Prepared by Reviewed by Approved by

Name:
Signature:

Date:

Requirements:

The following data should be fulfilled in case of submitting secondary standard

- Reference materials are standardized against
  a) Official compendial standard with evidence of validity e.g. being current lot, or with Batch validity statement

b) Certified reference material (CRM) supplied by ISO 17034 accredited RMP with certified value accompanied with uncertainty.
c) Primary in house with evidence of characterization of the assigned value.

- Identification testing: FTIR or two other confirmatory techniques e.g. HPLC, UV… to be against the data with that of the pharmacopoeia standard (attached spectra or chromatograms)
- Water content results in triplicates with raw data attached to worksheet.
- Purity Assigning testing (assay): At least at least in triplicates preparation with 2 or 3 injections for each preparation (with raw data attached to worksheet)
- Acceptance criteria for assay: to be calculated on dried basis or as is basis