APPENDIX 2 – VERIFICATION

PRINCIPLE

1.0 This Appendix describes the principles of verification which are applicable to the manufacture of traditional medicines (TM) products.

Accordingly, and in this Appendix, verification shall refer to the documented act or conduct of confirmation that the control or procedure required in a particular critical aspect of manufacturing operation has been complied with or satisfactory implemented by the manufacturer based on risk assessment and risk management.

Re-verification shall be performed if there are significant changes to the facilities, systems, processes and equipment that may have impact on the quality of the finished products, and the changes would require regulatory approval. Where there are no significant changes, periodic review shall be performed to show that the facilities, systems, processes and equipment continue to meet the prescribed requirements.

DOCUMENTATION

2.0 A Verification Programme which includes written procedure(s) shall be established to specify how the verification activities will be carried out. The documentation provided will demonstrate the quality assurance (QA) systems needed to produce quality traditional medicines. This includes the QA systems, which consist of elements that address matters such as roles and responsibilities, employee training, document management, equipment calibration and maintenance, manufacturing and laboratory control procedures, and product shelf life evaluation.

A report that cross-references the verification programme and procedure shall be prepared, summarizing the results obtained, commenting on any deviations observed, and drawing the necessary conclusions, including the recommending changes necessary to correct the deficiencies.

VERIFICATION OF MACHINERY AND EQUIPMENT

3.0 Equipment and machinery shall be periodically verified to determine if they are still operating in a valid state.

During verification it is important to use calibrated reference material e.g. NIST traceable calibrated thermometer to verify the temperature of process to determine its valid state.

Machinery and equipment to be used shall have been verified prior to the verification of process and staff taking part in verification work shall have been appropriately trained.

VERIFICATION OF PROCESS

4.0 General

Verification of process contributes to assuring product quality and the basic principle of quality assurance is that a product shall be produced under such condition that is fit for its intended use.

The basic principle of quality assurance is that a product shall be consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation and product specification.

5.0 Verification of process may involve demonstration, testing & analysis and in-process control, or other relevant to confirm that critical processes are kept under control. A process verification report shall be prepared to provide evidence that the process has been verified.

a) Demonstration.

Demonstration is the operation of an item to provide evidence that it can meet its predetermined specifications and quality attributes.

Demonstrations can be conducted in actual or simulated environments.

b) Testing & Analysis

Test is the application of scientific principles and procedures to determine the properties or functional capabilities of items. Test is similar to demonstration, but is more exacting, generally requiring specialized test equipment, configuration, data, and procedure in order to verify that the item satisfies the requirement.

Analysis is the use of established technical or mathematical models or simulations, algorithms, or other scientific principles and procedures to provide evidence that the item meets its stated requirements.

c) In-process control

Critical parameters shall be determined and monitored, checks performed during production in order to monitor and if necessary to adjust the process to ensure that the products confirm to its specification. The control of the environment or equipment may also be regarded as a part of in-process control.

Change control

6.0 Written procedures shall be in place to describe the actions to be taken if a change is proposed to a starting material, product component, process equipment, process environment (or site), method of production or testing or any other change that may affect product quality or reproducibility of the process. Change control procedures shall ensure that sufficient supporting data are generated to demonstrate that the revised process will result in a product of the desired quality, consistent with the approved specifications.

7.0 All changes that may affect product quality or reproducibility of the process shall be formally requested, documented and approve by the relevant department. The likely impact of the change of facilities, systems and equipment on the product shall be evaluated, including risk analysis. The need for, and the extent of, re-verification of machinery and equipment and re-verification of process shall be determined.