POLICY ON PRODUCT TRANSFER

INTRODUCTION:

Transfer of product to manufacturing site (new/alternate) occurs at some stage in the life-cycle of most products. This document provides the policy for product transfer from sending unit to receiving unit.

SCOPE:

This policy is applicable to all the new / existing products being transferred within ……., associated companies of .. or contract manufacturing sites of ……..

POLICY DETAILS:

- ✧ Written procedure shall be in place for product transfer activity.
- ✧ Product transfer shall be a joint responsibility of sending unit and receiving unit. Responsibility matrix shall be in place for each sub activity of product transfer.
- ✧ Product transfer shall be based upon principles of Quality Risk Management, considering Critical Quality Attributes (CQA), Critical Material Attributes (CMA) and Critical Process Parameters (CPP).
- ✧ cGMP procedures/practices shall be ensured during product transfer.
- ✧ The capabilities of the sending unit and receiving unit shall be similar but not necessarily identical and facilities and equipment shall operate according to similar operating procedure.
- ✧ In case it is not similar, equivalence study for the same shall be performed.
- ✧ Product transfer activity shall be carried out and documented as per approved protocol.
- ✧ Any non-conformance (deviation) observed during product transfer activity shall be investigated and documented.
- ✧ Product transfer report with summary and conclusion shall be reviewed by sending unit and receiving unit and shall be finally approved by Quality Assurance.
- ✧ Product transfer document along with its supporting data shall be retained as per defined policy.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION:

Product Transfer:

A logical procedure that controls the transfer of any process together with its documentation and technical expertise between development and manufacture or between manufacturing sites.

Sending unit:

The unit which is transferring the product.

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Receiving units:

The unit to which the product transfer is made.

ABBREVIATIONS:

cGMP: current Good Manufacturing Practices
WHO: World Health Organization

REFERENCES:

WHO Technical Report Series No. 961, 2011, Annex 7: WHO guidelines on transfer of technology in pharmaceutical manufacturing.