

POLICY ON RELEASE - REJECTION BATCHES

INTRODUCTION:

This document outlines policy to release / reject batches manufactured by

SCOPE

The policy applies to all batches of drug products and drug substances manufactured at, associated units meant for commercial distribution and for batches manufactured for pilot bio-study, bio-study and registration batches for non-commercial purpose.

POLICY DETAILS

- ✧ There shall be procedure in place for Batch Release/ Rejection to ensure that no rejected product is placed in distribution.
- ✧ Each batch of every product manufactured in shall be approved by designated person or his designee in Quality Department before being released for its intended purpose or distribution. The designated persons shall be formally identified and shall have appropriate qualification, training and experience in compliance with local requirements.
- ✧ Production and Quality Control records shall be reviewed as a part of approval process of batch release.
- ✧ In case of batches for export it shall be ensured that the batch is meeting all the marketing authorisation requirements.
- ✧ Any divergence or failure of a batch to meet its specification shall be thoroughly investigated.
- ✧ For any validation batches as a part of batch approval process for release it shall be ensured that the acceptance criteria requirements as per the validation protocol are met.
- ✧ The designated person or his delegate shall certify the release / reject the batch for its intended use.

AMENDMENT AND WAIVER:

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

DEFINITION: Not Applicable

ABBREVIATIONS: Not Applicable

REFERENCES: Not Applicable