POLICY ON RETENTION SAMPLES

INTRODUCTION:

This document provides the policy for Retention Sample (Reference sample).

SCOPE:

This policy is applicable to Raw materials, APIs, Excipients, Intermediates, Printed / Primary packaging materials and Drug products (formulations) in the final packs at ……. and associated units.

POLICY DETAILS:

- ✧ Retention samples for all starting materials, packaging materials, drug substance and packed finished products (other than solvents, gases or water used in the manufacturing process) shall be collected and maintained as per …….. laid down procedures and required by the local regulatory requirements.
- ✧ Retention samples shall be representative of the batch from which it was taken.
- ✧ Retention sample pack shall resemble the final packing of the drug product. In case of drug substance, retention sample shall be stored in equivalent or more protective pack than marketed pack.
- ✧ All retention samples shall be stored in temperature controlled environment, duly labelled and having proper traceability and ease for retrieval.
- ✧ Retention samples shall be retained for the period as mentioned in respective SOP.
- ✧ Retention sample storage area shall be monitored routinely for the temperature conditions maintained.
- ✧ The retention samples shall be of sufficient size to permit the carrying out full analytical testing on two occasions unless otherwise specified for a particular case.
- ✧ In case a batch is packed in two different packs, retention sample of each pack shall be maintained. Access to retention samples storage area shall be restricted.
- ✧ Withdrawal of retention sample shall be approved by Unit Quality Assurance Head. Retention samples of rejected materials / products, shall not be retained.
- ✧ Destruction of Retention Samples shall be documented.

AMENDMENT AND WAIVER:

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

DEFINITION: Not Applicable

ABBREVIATIONS:

API	:	Active Pharmaceutical Ingredient
CFR	:	Code of Federal Regulations
EU	:	European Union
GMP	:	Good Manufacturing Practices
SOP	:	Standard Operating Procedure
TRS	:	Technical Report Series
WHO	:	World Health Organization

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REFERENCES:

EU Guideline : EU GMP guideline (Annexure 19), Dated 14.12.2005. CFR Guideline : 21CFR, part 211.170
TRS 937 : Technical report of WHO, regulatory.

TRS 908 : WHO Expert Committee on Specifications for Pharmaceutical Preparations