POLICY ON WORKING STANDARDS

INTRODUCTION:
….……understands that usage of Woking standards as per Pharmacopoeia requirements to comply with various regulatory authorities to ensure that the products are of the appropriate identity, strength, quality, purity and consistency.

SCOPE:
This policy is applicable to plan and implement working standards programme in QC.

POLICY DETAILS:

- ‘Working standards’ to be prepared in comparison with current lots of respective pharmacopoeia ‘Reference standards’.
- Written procedures/SOP shall be available for qualification, storage, consumption, requalification and traceability to be maintained throughout ‘WS’ life cycle.
- Predetermined schedule for qualification to be prepared and executed, same to be monitored with predetermined frequency.
- Combined ‘WS’ i.e. IP/BP/EP (Ph.Eur)/USP etc. can be prepared with respective ‘RS’ evaluation. Storage and transport conditions to be defined to take care of degradants.
- Re-qualification to be done prior to expiry of existing ‘WS’. Validity to be derived by studying the stability of molecule.
- Monitoring for lot change to be done on predefined frequency so as ‘WS’ to be updated with Pharmacopoeia lots.

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

DEFINITION: Not Applicable

ABBREVIATIONS:

BP	:	British Pharmacopoeia
IP	:	Indian Pharmacopoeia
EP	:	European Pharmacopoeia
QC	:	Quality Control
SOP	:	Standard Operating Procedure
USP	:	United States Pharmacopoeia
WS	:	Working standard
RS	:	Reference standard

REFERENCES:

USP	: General Chapter <1010>
USP	: General Chapter <11>
EP	: General Texts 5.12
IP	: IPRS site