

STANDARD OPERATING PROCEDURE (S.O.P)

تعليمات

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Date: / /	Date: / /	Date: / /	Copy No. :
1.Purpose(الغرض): 2.Scope : مجال التطبيق	To provide instructions for the process of reporting, investigating & handling deviations from defined procedures and processes. 2.1 Documents covered under the scope of this standard operating procedure include the following, but are not limited to: • Standard Operating Procedures. • Manufacturing Procedures. • Packing Procedures. • Cleaning Procedures. • Environmental Monitoring. • Batch analysis (In-Process Control). • Utility Operations. • Calibration Procedures. 2.2 Out –Of Specifications (OOS); analytical results & stability results are not covered by this instruction and are detailed in (QQI-527). 3.Responsibility: المسئولية		
3.1 It is the responsibility of each production function/department to follow the procedure and system by which the root causes of deviation are identified, investigated and documented. 3.2 It is the responsibility of each production function/department to undertake and track appropriate and timely corrective and preventative actions. 3.3 It is the responsibility of Quality Assurance to approve deviation reports prior to product release decision.			

Sop Pharmaceutical Management Review Gmp Manual

ML Morrison



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