SAFC®

Pharma & Biopharma Raw Material Solutions

MERCK

Quality-Related Deliverables for Synthetic Lipids

- **Standard service of Merck**
- **Recommended service initiation and partial implementation upon request; alignment between Quality (Q) Units is recommended**
- **Optional service; available upon request (in-house capability in place)**
- **Not required; not offered**

Topic	Phase I/II	Phase III	Phase IV	Comment
Quality System Processes				
GMP Training	●	●	●	Employees are educated on GMP guidelines
Double-Check Principle in QC	●	●	●	Independent double-check: release results and critical steps
Self-Inspection	●	●	●	All GMP departments are inspected annually by Q Unit
Change Management	●	●	●	Phase I/II: changes are released via batch record; significant changes are released via formal process (QA is involved) Phase III: formal change control process
Deviation Handling	●	●	●	Phase I/II: evaluation of batch record; significant deviations are handled via formal process Phase III: formal process, including investigation and (CAPA) measurement setting
CAPA Management	●	●	●	Formal corrective and preventive actions after critical deviations
OOS Handling (investigation to assess rejection or release)	●	●	●	Phase I/II: final product
Complaint Management	●	●	●	Incoming complaints are formally handled and investigated
Qualification Processes				
Area Qualification (production)	●	●	●	Critical production areas (i.e., manufacture, logistics) are qualified and monitored
Equipment Qualification (production)	●	●	●	Lab scale: qualification and maintenance of major equipment Production scale: qualification and maintenance of all equipment
Equipment Qualification (QC-lab)	●	●	●	Qualification and maintenance of analytical equipment
Equipment Maintenance/Equipment Calibration Control and Monitoring of Measuring Device (incl. reagents)	●	●	●	Calibration of critical equipment
Computer Validation (lab)	●	●	●	Critical calculations (i.e., assays) are performed in a validated Excel sheet (ERP/LIMS)
Process Validation	●	●	●	Preparation during Phase III (complete validation during Phase III is available upon request)
Cleaning Validation	●	●	●	Cleaning methods are validated to prevent cross-contamination of other products
Cleaning Verification	●	●	●	Cleaning procedures are verified to prevent cross-contamination

Topic	Phase I/II	Phase III	Phase IV	Comment
Qualification Processes				
Supplier Approval/Qualification of Raw Material	●	●	●	Critical raw material suppliers are qualified and released
Supplier Qualification Primary Packaging Material (if not standard material)	●	●	●	Primary packaging material suppliers are qualified and released
Analytical Processes				
Analytical Method Validation	●	●	●	Validation of critical analytical methods
Stability Studies	●	●	●	Stability studies are conducted to determine retest period and storage conditions (e.g., Phase I: gain product knowledge, including degradation products; Phase II: find optimal containment system and storage conditions; Phase III: determine retest period)
Stability Studies According to ICH (long-term conditions)	●	●	●	Long-term study: confirmation of retest period
Impurity Profile	●	●	●	Specifications are defined and justified; impurities are specified and, if necessary, identified
Microbiological Testing Final Product	●	●	●	Bio-burden and endotoxins are tested for release
Incoming Goods Test of Each Batch (specification check)	●	●	●	Raw material is at least CoA tested
Other Processes				
ISO14001	●	●	●	EHS guidelines are implemented
Storage Location – Definition of Minimum GMP Requirements	●	●	●	Storage is defined and localized in a qualified, controlled, and monitored environment
Pest Control	●	●	●	Critical areas are pest controlled
Documentations (Non-Exhaustive List)				
Justification of Specification	●	●	●	See ‘Impurity Profile’
CTD Description of Process	●	●	●	CMC section writing
DMF	●	●	●	DMF filing
CoS[1]	●	●	●	Only if monograph is available
BSE/TSE Certificate	●	●	●	BSE/TSE safety confirmation
Stability Reports	●	●	●	Stability data/retest period & storage conditions
CoA/ADS	●	●	●	Certificate of Analysis/Analytical Data Sheet
CoC	●	●	●	Certificate of GMP Compliance

[1] Certification of Suitability of the monographs of the European Pharmacopoeia

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