MNQ Consultants	**Completed Audit Checklist/ Audit Report – cGMP for Cosmetics Products Manufactured at Shankara**	Doc. No.	**2024-01 Audit**
		Revision	A

Audit Report for Shankara Products Audit August 2024
Focus for cGMP was 21 CFR 210/21 CFR 211
Audit Date: 21 August 24 Report Completed and sent on 8/26/24

	Requirement	Yes	No	N/A	Comments
	21 CFR Part 211 CURRENT GOOD MANUFACTURING PRACTICE Applied to Cosmetic Manufacturing				
Standard Ref.	**Subpart B—Organization and Personnel (Note: See Subpart A for Scope and Definitions)**				
211.22 211.22(b)	Is there a quality control (QC) unit with approval/ rejection responsibility and authority? Does the QC have the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated? Are the laboratory facilities adequate for testing and approval/rejection process?	Y N/A			Only visual testing done in house. Microbial tests done at Microchem Labs No in house testing carried out at Shankara.
211.22(d)	Are there written procedures outlining the responsibilities and procedures applicable to Shankara? Are they followed? Note: Quality Manual and Quality Policy in place? Quality Manual, Rev D training was conducted as part of the pre audit on 8/20/24 and 8/21/2024.	Y			See SOP-05, Rev A Quality policy is posted across the building. Q. Policy reviewed and deemed as current by CEO. Reviewed training records for Quality manual and found it to be satisfactory. Quality Manual updated as needed.
211.25 211.34	Do employees, supervisors, and consultants have the necessary education, training, and experience to enable that person to perform the assigned functions? Requested Sudha's and Nikhil's CVs and Job descriptions for Production Associate and Sushma's for Production Manager.	Y			It was noted that the Title had changed in the Org. Structure for Sushma from Lead Production Associate to Production Manager. This was corrected during the audit. No further action needed.
211.25	Are employees trained in current GMP on a continuing basis to assure that employees remain familiar with cGMP requirements applicable to them? Quality Manual Training was completed in lieu of GMP for 2024 as requested by CEO during Audit Prep.	Y			Past training records reviewed and training record from Training conducted on 8/20/24 as part of pre audit on site was reviewed also during the audit by the auditor.
	Org Chart was reviewed. It was noted that the President of Shankara had Production responsibilities while the newly created position of Quality Director will oversee Production QA and QC reporting to the President and VP of Compliance.	Y			Org Chart last updated on**:** 8/20/24. It reflects all positions moving forward after the audit. JDs in place. Note: Shankara Quality Consultant is now hired as Quality Director following this audit conducted by the consultant.

Standard Ref.	Requirement	Yes	No	N/A	Comments
211.25(c)	Is there an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each Cosmetic product?	Y			Currently adequately staffed. Separate staff assigned for distribution of products from Sri Sri Tatva, Shankara's vendor partner whose products are distributed from designated areas of Shankara's warehouse. Sri Sri Tatva is just a co user of Shankara's warehouse at this point.
211.28(a) 211.28(c)	Do personnel wear clean clothing appropriate for the duties they perform, including protective apparel worn as necessary to protect Cosmetic products from contamination? Are areas of facilities and buildings designated as limited access areas only accessible to personnel authorized by supervisory personnel?	Yes	 No		Gowning room labelled appropriately. Employees follow gowning rules well. Noticed an employee who wore the face mask while filling for final packaging. No building access restrictions. All key personnel have access keys for the building.
211.28(d)	Are personnel shown to have illness/ lesions that may adversely affect the safety or quality of Cosmetic products excluded from direct contact with components, containers, closures, in-process materials, and Cosmetic products?	Yes			Signs posted at entrance and rest rooms.
211.34	Are records maintained stating the name, address, and qualifications of consultants and the type of service they provide?			N/A	No consultants used currently except a volunteer who helped out Facility Registration for 2024.
	Subpart C—Buildings and Facilities				
211.42	Is there adequate lighting and ventilation in all areas? Clear segregation between products?	Yes 			Well-lit facility with good ventilation in all areas. Only cosmetics manufactured at this facility.
211.44 211.46	Is there adequate lighting and ventilation in all areas?	Yes			Well lit facility with good ventilation in all areas.

	Requirement	Yes	No	N/A	Comments
211.46(b)	Is equipment for adequate control over air pressure, microorganisms, dust, humidity, and temperature provided (where appropriate)?	Yes			Weather sealed windows, gowns and hair nets, gloves used by production personnel.
211.46(c)	Are air filtration systems used on air supplies to production areas? Where air contamination occurs during production, are there adequate exhaust systems or other systems adequate to control contaminants?	Yes			HVAC system and air filtration systems appeared to be maintained well
211.48(a)	Is potable water supplied under continuous positive pressure in a plumbing system free of potentially contaminating defects?	Yes			Water system maintained well per industry expectation. Purified/distilled water used for production of water-based products is purchased in bottles.
211.48(b) 211.50	Are drains of adequate size and, where connected directly to a sewer, provided with an air break or other mechanical device to prevent back siphonage? Is sewage, trash, and other refuse in and from the building and immediate premises disposed of in a safe, timely, and sanitary manner?	Yes			No sign of water accumulation, product debris in the building. Trash cleaned up routinely. Building is cleaned by contractors. All shipment related boxes are recycled appropriately.
211.52	Are adequate washing facilities provided, including hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accessible to working areas? Is the facility maintained at Controlled Room Temp and Humidity required for manufacturing facilities?	Yes			Entire facility is well maintained for these items. Temp. and humidity are monitored. Reviewed 3 charts and found temperature and Relative humidity being monitored. Excursions are reviewed. There is room for improvement here for additional attention for compliance although changes observed are not excessive now.
211.56(a)	Are facilities maintained in a clean and sanitary condition? Is building free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals)?	Yes			Rodent traps maintained by 3rd party providers. See SOP -04 for facility maintenance. Confirmed current monthly service.

	Requirement	Yes	No	N/A	Comments
211.56(b) 211.56(c)	Is there a written procedure assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning facilities? Are written procedures followed? Are there written procedures for use of suitable (e.g. registered) rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents designed to prevent contamination? Are the procedures followed?	Yes			See SOP -04 for facility maintenance. All cleaning contracted out for weekly and Biweekly cleanings. Professional Pesticide management company provides routine pest control services. Confirmed evidence of insect traps' oversight by Pest Control company during the audit.
211.58	Are buildings used in the manufacture, processing, packing, or holding of a Cosmetic product maintained in a good state of repair?	Yes			Observed some stain at the front entrance of the building which has not caused any leak issues. Building is leased and owner will correct issues if needed.
	Approved Supplier List (ASL) was looked at and gaps were found in it. • Table was incomplete as it had empty cells. • Title, Form # and rev # was missing on the ASL • Add a Note on suppliers who provide off the shelf products do not need to be on ASL and state the frequency of ASL update				Reviewed NC#1, from 2023 audit corrected through CAPA 09. Corrected satisfactorily. However, it was noticed that 2 Onboarding documents were not returned/ missing but seen in the ASL. Row 20: Lucas Meyer Cosmetics and Row 7 Container and Packaging. This is being called out as **NC#1**. Other updates were suggested as **OFI #1** to improve the ASL such as fill out the empty spots on ASL for Supplier Quality Verification by looking at their website, so a close eye is kept on the global supply chain for Shankara.
	Subpart D—Equipment				

Additional Notes: N/A

	Requirement	Yes	No	N/A	Comments
211.67	Are written procedures established and followed for cleaning and maintaining equipment / utensils? Do these procedures cover: a. Assignment of responsibility for cleaning/ maintaining equipment b. Maintenance and cleaning schedules c. Description of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance d. Removal or obliteration of previous batch identification e. Protection of clean equipment from contamination f. Inspection of equipment for cleanliness immediately before use Are records of maintenance, cleaning, sanitizing, and inspection kept? Checked for PM/ Cal on production equipment.	Yes Yes			Equipment cleaning performed after each batch and verified before usage for the next batch as part of Manufacturing procedures. Equipment not under current use is kept covered. Looked at cleaning records before and after manufacturing as part of the batch records. Calibration weights PM/Cal checked. OFI #2 is: Bracketing weights not adequate for one set of balances. Need to obtain 1 gm weight as 0.1 gm is not readable repeatedly on several balances used for low end weighings.See below details under OFI #2. .
211.68(a)	If automatic, mechanical, or electronic equipment is used, is it routinely calibrated, inspected, or checked according to a written program? Are written records of those checks and inspections maintained? Note: Balance I5500 in Measuring room was noticed to have only 10 gms and 2 Kgs for calibration. The low end is not covered although low weights such as 1 gm is being measured. This was pointed out as a gap during the audit. Quote was requested for 1 gm weight during the audit	Yes	No		**OFI #2** from Audit of 2024: Calibration weight bracketing standards need additional attention for extra accuracy. Noted the need for lower end weights such as 1 gm to appropriately Already corrected during the audit Reviewed NC #3 from 2023 Audit for gaps noticed in balance calibrations. This was corrected through CAPA

					011 satisfactorily and now weekly calibration is in place for all balances in the Shankara facility.
QSR	Requirement	Yes	No	N/A	Comments
211.68(b)	Are appropriate controls exercised over computer systems or related systems to assure changes in master production and records are instituted only by authorized personnel? Is input and output from the computer or related system of formulas or other records or data checked for accuracy? Is the frequency of verification based on the complexity and reliability of the computer or related system?	Yes			"Fish Bowl" software used for inventory and order management has its security and user authentication controlled. Being updated to a new system called Simuletics. Reviewed Work Orders W 24612, 24613, 24594, 24495 and 24496 during the audit. Adequate QC Checks and Work order review and approvals have been put in place, showing Shankara Management's commitment to continuous quality improvement for its production facility that seems to be growing with new products and higher volumes for established products.
211.68(b)	Is there a backup file of data entered into the computer or related system maintained? Are hard copy or alternative systems maintained and designed to assure that backup data is secure from alterations or loss?		No		The data is stored in the cloud and maintained with backups.
211.72	Where liquid filtration filters are used in the manufacture, processing, or packing of injectable Cosmetic products intended for human use, do they comply with the following: - Prevented from releasing fibers? - If fiber-releasing, is it used with an additional non-fiber releasing filter? - No asbestos?	Yes		N/A	All filtration systems are well maintained and kept thoroughly clean and dry.

	Subpart E—Control of Components and Cosmetic Product Containers and Closures				
QSR	**Requirements**	**Yes**	**No**	**N/A**	
211.80(a)	Are there written procedures describing the receipt, identification, storage, handling, sampling, testing, and approval/rejection of components and Cosmetic product containers and closures? Are procedures followed?	Yes			There is a SOP for Product Receiving/ packaging, SOP-01.
211.80(b)	Are components and Cosmetic product containers and closures handled and stored in a manner to prevent contamination?	Yes			Containers are kept in order.
211.80(c)	Are bagged or boxed components of Cosmetic product containers or closures stored off the floor and suitably spaced to permit cleaning and inspection?	Yes			Warehouse is very clean and organized.
211.80(d)	Is each container or grouping of containers identified with a distinctive code for each lot in each shipment received? Is this code used in recording the disposition of each lot, allowing for the lot to be identified as to its status (i.e. quarantined, approved, rejected)?				Evidence of FIFO (First in First out) practice seen during the tour. Discussed with the employees FEFO (First Expiry First Out) during the audit for increased cGMP awareness.

211.82(a) 211.82(b)	Upon receipt and prior to acceptance, is each container or grouping of containers examined visually for appropriate labeling, damage, and contamination? Are components, containers, and closures stored under quarantine until they have been tested or examined and released?	Yes			Shankara SOPs clearly define these requirements. Release requirements are followed.
QSR	**Requirement**	**Yes**	**No**	**N/A**	**Comments**
211.84(a)-(b) 211.84(c) 211.84(d) 211.84(e)	Is each lot withheld from use until it has been appropriately sampled, tested, or examined and released by the QC unit? Is the number of samples taken based on appropriate criteria? Are samples collected appropriately, including cleaning and sterilization to prevent contamination? Are samples tested appropriately, including tests for identity, conformity with specifications, and contamination? Are lots of materials that do not meet specifications rejected?	Yes			Reviewed W.O. W 24496.001. Found to be satisfactory. . Retain samples are stored for each batch (since Feb 2024). Microbiological test samples are to be sent periodically per SOP-05. None have been sent in 2024. OFI is to send at least 5 randomly chosen samples/year for microbial testing and update the SOP accordingly. Per SOP-20 for New Product Development micro tests are still done. Microbiological testing may be done for water-based products as part of complaint investigations (SOP-011).
211.86	Are components, containers, and closures approved for use organized so that the oldest stock is used first?	Yes			FIFO is well implemented at all stages of production.

211.87	Is retesting performed as necessary (e.g. after storage for long periods or exposure to air/heat)?		No	N/A	Retesting is not necessary. 6-month expiration after opening claimed now. Retain samples will be tested if needed.
211.89	Are rejected materials identified and controlled to prevent use in operations for which they are unsuitable?	Yes			When a product is rejected, documentation is not adequate at this point. Eg; with suppliers through email only now as opposed to SCARs. **OFI#3**

	Requirement	Yes	No	N/A	Comments
211.94(d)	Are there documented standards or specifications, testing methods, and (where indicated) methods of cleaning/sterilization for Cosmetic product containers and closures?			N/A	No in house testing other than visual inspection for QC testing.
211.94(b)	Do container closure systems provide adequate protection against foreseeable external factors in storage and use that can cause contamination?	Yes			Whole facility maintains good temperature controls. Temperature and Humidity monitors are in place in production Rooms.
211.94(a)(c) 211.94(e)	Are Cosmetic product containers and closures clean and (where appropriate) sterilized? Are they designed so as not to alter the Cosmetic? Do medical gas containers and closures meet the requirements of including required gas-specific use outlet connections and proper labeling?	Yes			Containers are verified visually for cleanliness. When packaging/pumping mechanism defects are noticed, Shankara Production Manager notifies the supplier via email and rejects the defective materials. This informal communication and rectification process is not per cGMP. See OFI #3 on Page 8.

					It should include this supplier communication process streamlining via SCARs (Supplier Corrective and Preventive Action).
	Subpart F—Production and Process Controls				
211.100(a)	Are there written procedures for production and process control to assure that Cosmetic products have the identity, strength, quality, and purity they are represented to possess? Are these procedures drafted, reviewed, and approved by appropriate organizational units and QC? How are new products designed and onboarded to production? Are labelling for all products completed at Shankara? It was noted that some products are called vendor partnered products and are distributed from Shankara Warehouse.	Yes			Manufacturing procedures are being written for each product. See Project Plan for MP Updates dated 8/20/24. 2 of the 25 completed (new and improved 1.MP- 402: Manufacturing Procedure-SF077-Raffermine 2.MP-022: Manufacturing procedure balancing oxygenating mask. Minor typos were corrected during the audit forMP-022.
QSR	**Requirements**	**Yes**	**No**	**N/A**	**Comments**
211.100(b)	Are procedures documented at the time of execution and performance of the relevant functions, including justifications for any deviations?	Yes			Work orders reflect the building of each lot. The Manufacturing Procedures (MPs) are being updated for ease of production and associated training. The plan is to have all MPs updated by October 2024.Justifications for deviations are handled on a case-by-case basis.
211.101(a), b, c	Is the batch formulated to provide not less than 100% of established active ingredients? Weighing and measurements controlled?	Yes			Work Orders are being reviewed and approved for yields as the production batches are completed.
211.101(b)-(c)	Are components weighed, measured, or subdivided as appropriate? Is this process supervised by a second person?	Yes			Not supervised by a second person but all work orders are reviewed and signed off.

211.101(b)	Where components are removed from the original container to another, is the new container able to be appropriately identified?	Yes			Yes. Saw intermediate labeling practices.
211.101(d)	Is each component added to the batch verified by someone other than the person/equipment that added it?		No		They are approved on Work orders
211.103	Are yields determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding? Is yield verified outside of the person/equipment that calculated it?	Yes			Yields are calculated and documented in WOs
211.105(a)-(b)	Is all equipment used during production properly identified by a distinctive identification number recorded in the batch production record?	Yes			Noticed evidence for this during the plant tour.
QSR	**Requirement**	**YES**	**NO**	**N/A**	**Comments**

211.110(a)	Are written procedures established to assure batch uniformity and integrity of cosmetic products? Do these include at least the following, where appropriate: - weight variation - Adequacy of mixing to assure uniformity and homogeneity. - Clarity, completeness Are in-process specifications consistent with final specifications, and assure that the product and material conform to specifications? Are in-process materials inspected and approved or rejected by QC during the production process?	Yes Yes			If specs are not met, products are discarded and documented accordingly on a case-by-case basis. Documented in batch records.

211.110(d)	Are rejected in-process materials controlled to prevent use in operations for which they are unsuitable?	Yes			Yes. Notification sent via email to supplier in most cases. **OFI#3** is to formalize this notification to suppliers through Supplier Corrective Actions.
211.111	Are time limits for completion of each phase established where appropriate to assure quality? Are deviations acceptable (i.e. do not compromise quality) and justified and documented?	yes			This is part of the work order.
211.113	Are written procedures established and followed to prevent objectionable microorganisms of nonsterile products or microbiological contamination of sterile products (including validation of aseptic and sterilization processes)?		No		Yes. In SOP-05. Micro testing is outsourced.
211.115	Are written procedures established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications? Is all reprocessing approved by QC prior to performance?	Yes			Examples of disposal discussed during the audit. No complete batch was discarded and so no sample documentation was available for review during the audit. See OFI #3 for details.
	Subpart G—Packaging and Labeling Control				

211.122(a)	Are there written procedures regarding the labeling and packaging materials?	Yes			See SOP-01 and SOP-09.
211.122(c)	Are records maintained for each shipment received of labeling and packaging materials indicating receipt, examination, and whether accepted or rejected?	Yes			See SOP-01. All relevant SOPs reviewed during the audit.
211.122(d)	Are labels for different products, strengths, dosages, or quantities stored separately with suitable identification? Is access to the storage area limited to authorized personnel?	Yes			See SOP-01 and SOP-09.
211.122(e)	Are obsolete/outdated labels or packaging materials destroyed?	Yes			Part of SOP-01.

	Requirement	Yes	No	N/A	Comments
211.122(f)	Is gang-printed labeling for different products or different strengths or net contents of the same product either avoided or limited to labeling adequately differentiated by size shape or color?	Yes			Label printing is outsourced to a supplier on ASL.
211.122(g)	Is a special control procedure in place for labeling and packaging using cut labeling for immediate container labels, individual unit cartons, or multi-unit cartons containing immediate containers that are not packaged in individual unit cartons?				
211.122(h)	Are printing devices used to imprint labeling monitored to assure that all imprinting conforms to specifications?				SPA Products and Amazon bound products have in-house labels. Reviewed during warehouse tour during the audit.

211.125(a), (b), (f)	Is labeling strictly controlled, including examination for identity and conformity to specifications? Are written procedures in place describing control for issuance of labeling?	Yes			Labels are controlled per SOP-09. No gaps noticed during the 2024 Internal audit.
QSR	**Requirements**	**Yes**	**No**	**N/A**	**Comments**
211.125(c)	Are procedures used to reconcile quantities of labeling with quantities of finished Cosmetic products (unless 100-percent examination is performed for cut/roll labelling or wraparound labels on portable cryogenic medical gas containers)? Are discrepancies outside narrow preset limits investigated?	Yes			Only needed labels are printed
211.125(d)	Are all excess labeling bearing lot/control numbers destroyed?	Yes			Destruction handled appropriately
211.125(e)	Is returned labeling maintained and stored to prevent mix-ups?	Yes			Systems in place to prevent mix ups.

	Requirement	Yes	No	N/A	Comments

211.130	Are there written procedures in place to assure that correct labels, labeling, and packaging materials are used? Are they followed? Do the labeling/ packaging procedures incorporate the following: - Prevention of mix-ups - Identification of unlabeled Cosmetic products set aside for future labeling - Identification of Cosmetic product with lot/control number - Inspection and documentation of inspection of packaging and labeling materials before packaging operations - Inspection of packaging/labeling facilities immediately before use, including assurance that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection documented in batch production records	Yes			Labels are printed and applied appropriately. Some labels for products sold in the US come in for distribution in the US pre applied from an Indian subsidiary. Samples of these were verified.
211.132	Do all cosmetic products comply with tamper-evident packaging requirements, including tamper-evident packages distinctive by design and labeling identifying all tamper-evident features?	Yes			Several examples of products were looked at as evidence.
211.134	Are packaged and labeled products examined to provide assurance of correct label? Are results of sample examinations recorded in batch production or control records?	Yes			Label verification is part of product release.
211.137(a)(b) 211.166	Do labels bear an expiration date (related to storage conditions stated on the labeling) determined by appropriate stability testing?	Yes			Expiration dating is 6 months after opening as established for stability.

Additional Notes: N/A

	Requirement	Yes	No	N/A	Comments

211.137 (e)-(g)	This does not apply to allergenic extracts labeled “No U.S. Standard of Potency” or homeopathic Cosmetic products			N/A	
211.137(c)	Do reconstituted products bear expiration information for both reconstituted and non-reconstituted Cosmetic products?	Yes			Expiration dating is 6 months after opening or 2 years and Expiration dates are followed through Manufacturing dates.
	Subpart H—Holding and Distribution				
211.142	Are there written procedures describing warehousing of Cosmetic products, including quarantine before QC release and storage under appropriate conditions? Are they followed?	Yes			SOP-04, Facility Management describes this.
211.150	Are there written procedures describing the distribution of Cosmetic products, including use of oldest approved stock first and maintaining distribution records of each lot to facilitate recall if necessary? Are the procedures followed?	Yes			SOP-06 describes this and is being followed per reviewed examples.
	Subpart I—Laboratory Controls				
211.165(a)	Does each batch of Cosmetic product have laboratory (lab) determination of satisfactory conformance to final specifications prior to release?	Yes			Final product QC verification is documented. No Lab testing on site.
211.165(b)	Is lab testing performed as necessary on each batch of Cosmetic product required to be free of objectionable microorganisms?	Yes			A qualified contract lab is used for micro testing
211.165(c)(e)	Do written procedures outline sampling and testing plans, including methods and numbers of units? Are procedures followed?	Yes			Sampling is done and documented in batch records.
211.165 (d)(f)	Are acceptance criteria for the sampling and testing adequate to assure batches meet specifications as a condition of their approval and release? Where reprocessing is performed on rejected products, are all appropriate specifications and standards met prior to acceptance and use?	Yes			Reviewed W.O# W24613 for Timeless Skin Oil.

	Requirement	Yes	No	N/A	Comments
211.166	Is there a written testing program implemented to assess the stability characteristics of Cosmetic products?	Yes			Stability is established by Shakara's R&D department located overseas. Sample documentation was shared and found to be acceptable.
211.167(a) 211.167(b)	Are written lab testing procedures implemented and followed to determine conformance of sterile and/or pyrogen-free products to such requirements? Are there written and followed lab test procedures regarding presence of foreign particles and harsh/abrasive substances for each batch of ophthalmic ointment? Are there written and followed lab test procedures to determine the conformance of the rate of release of each active ingredient for each batch of controlled-release dosage form?			N/A	
211.170(a) 211.170(b) 211.170 (b)	Is an appropriately identified reserve sample (twice needed for specification conformance tests) representative of each lot in each shipment of each active ingredient retained for the appropriate time? Is an appropriately identified reserve sample (twice needed for tests other than sterility/pyrogen) of each lot/batch of Cosmetic product retained and stored under conditions consistent with product labeling? (3 years for OTC product, 3-6 months past expiration date for radioactive product, and 1 year after expiration date for others Is the product reserve sample visually examined at least once a year for evidence of deterioration (unless radioactive or visual examination would affect integrity)? Are the results of the examination recorded and maintained with stability data on the product?	Yes			Reviewed SOP-019 which describes this process. Reserve samples were saved in the warehouse. Visual examinations are conducted as needed.

Additional Notes:

	Requirement	Yes	No	N/A	Comments
211.173	Are animals used in testing identified, maintained, and controlled in a manner that assures their suitability for their intended use? Are adequate records maintained showing the history of their use?			N/A	None
211.176	If a reasonable possibility exists that a non-penicillin Cosmetic product has been exposed to cross-contamination with penicillin, is the non-penicillin Cosmetic product tested for the presence of penicillin?			N/A	None
	Subpart J—Records and Reports				
211.180(a)	Are records associated with a batch of a Cosmetic product retained for the appropriate time? (i.e. at least 1 year after the expiration date of the batch or 3 years after distribution of OTC Cosmetic products lacking expiration dating)	Yes			Expiration is generally 2 years based on date of manufacture stated in W.Orders.
211.180(c)	Are records available for authorized inspection?	Yes			Reviewed during audit. Satisfactory.
211.180(f)	Are procedures established to assure that responsible officials are notified in writing of any investigations, recalls, reports of FDA inspections, or regulatory actions brought by the FDA?	Yes			SOP-011 describes this process. No gaps noticed during the GMP audit.
211.182	Is a written record of major equipment cleaning, maintenance, and use included in individual equipment logs that show the date, time, product, and lot number of each batch processed? Is it dated and signed/initialed indicating that the work was performed?	Yes			Part of the batch records.

Additional Notes:

QSR	Requirement	Yes	No	N/A	Comments
211.184(a)	Do records contain the identity and quantity of each shipment, name of the supplier, supplier lot numbers (if known), receiving code, receipt date, and name and location of the prime manufacturer if different from supplier?	Yes			Part of Batch records in Fishbowl software. This software is Part 11 compliant with built in security and authenticated users.
211.184(b)	Do records contain the results of any test performed and the conclusions derived?	Yes			Acceptable, no concerns
211.184(c)	Do records include an individual inventory record of each component, container, and closure?	Yes			Acceptable, no concerns
211.184(d)	Do records include documentation of the examination and review of labels and labeling?	Yes			Acceptable, no concerns
211.184(e)	Do records include the disposition of rejected components, Cosmetic product containers, closure, and labeling?	Yes			Acceptable, no concerns
211.186(a)	Are master production and control records for each Cosmetic product prepared, dated, and signed by one person and independently checked, dated, and signed by a second person? Is the preparation of master production and control records described in a written procedure that is followed?				Reviewed response to 2023 NC #4 for GMP Documentation gaps seen. Users retrained as part of CAPA 12.
211.186(b)	Do master production and control records include: - Name and strength of the product and description of the dosage form - Name and weight or measure of each active ingredient per dosage unit and a statement of the total weight or measure of any dosage unit - Complete list of components designated by names or codes - Accurate statement of the weight/measure of component	Yes			Batch records were seen to be complete and acceptable based on the samples reviewed during the audit.

	Requirement	Yes	No	N/A	Comments
211.186(b)	- Statement concerning any calculated excess of component - Statement of theoretical weight or measure at appropriate processing phases - Statement of theoretical yield (including max and min percentages beyond which investigation is required) - Description of the containers, closures, packaging materials, and labels - Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed	Yes			F001, product Inspection form for manufacturing has clear instructions.
211.188	Are batch production and control records prepared for each batch of Cosmetic product produced? Do batch production and control records include accurate reproduction of the appropriate master production or control record and documentation that each significant step was accomplished including dates, identity of used equipment and lines, sampling performed, etc.?	Yes			Part of Fish bowl software. Reviewed a few examples and found them to be satisfactory.

211.192	Are all Cosmetic product production and control records reviewed and approved by QC? Are any unexplained discrepancies or failures to meet specifications thoroughly investigated?	Yes		N/A	N/A Except for Micro testing contracted out by Shankara where all these practices are implemented.
211.194(a) 211.194(b)	Do laboratory records include complete data derived from all tests, including description of samples, methods, data, calculations, results, and appropriate signatures? Are complete records maintained of any modification of an established test method?	Yes		N/A	N/A Except for Micro testing contracted out by Shankara where all these practices are implemented.

Additional Notes: N/A

QSR	Requirement	Yes	No	N/A	Comments
211.194(c) 211.194(d) 211.194(e)	Are complete records maintained regarding testing and standardization of lab reference standards, reagents, and standard solutions? Are complete records maintained of periodic calibration of lab instruments and devices? Are complete records maintained of all stability testing performed?			N/A	No in house testing is carried out at Shankara.
211.196	Do distribution records contain the name and strength of the product, description of the dosage form, name and address of the consignee, date and quantity shipped, and lot/control number of the product?	Yes			Distributed products are well documented.
211.198(a)	Are there written procedures describing the handling of all written and oral complaints regarding a Cosmetic product? Are they followed?	Yes			Reviewed SOP 11 for complaint management. Main complaint is about smell or pump defects or packaging but none for product safety or efficacy.

211.198(b)	Are written records of complaints maintained in a file designated for Cosmetic product complaints? Do written records include the name and strength of the product, lot number, name of complainant, nature of complaint, and reply to complaint? Do complaint records include findings of investigations and follow up? Where investigations are not conducted, does the record include justification. System in place to handle Corrective and Preventive actions (CAPAs) encountered in the QMS (Quality Management System) at Shankara?	Yes Yes			None for product safety or efficacy. Complaint log maintained. Reviewed the 4 CAPAs completed from 2023 (although the closure was delayed and was completed during the 2024 pre-audit due to other priorities)
	Subpart K—Returned and Salvaged Cosmetic Products				
211.204	Are there written procedures for the holding, testing, and reprocessing of returned Cosmetic products, and are they followed?			N/A	Replacement products are generally provided to customers if needed. See SOP 14.

Additional Notes: N/A

	Requirement	Yes	No	N/A	Comments
211.204	When returned product or its container, carton, or labeling is doubtful on the safety identity, strength, quality, or purity of the product, is the returned product destroyed unless investigation proves the product meets appropriate standards?	Yes			

211.208	Are Cosmetic products that have been subjected to improper storage conditions prevented from being salvaged? Where Cosmetic products may have been subjected to improper storage conditions, are they prevented from being salvaged unless there is evidence from lab tests that the Cosmetic meets all standards/specifications and evidence that the products /packaging were not subjected to improper storage conditions? Are records including name, lot number, and disposition maintained? Customer complaints received and handled appropriately for cGMP Compliance?	Yes			Reviewed SOPs 01 for Receiving and packaging and SOP 11 for handling of complaints for cGMP compliance. Fully acceptable.
Internal audits	Reviewed documents related to 2023 Internal Audit as applicable to cGMP for Shankara	Yes			All 2023 CAPAS reviewed for completion and implementation. The 4 CAPAs were completed during 2024 Internal Audit preparation.
Quality Review	Are Management Reviews being Conducted? Management support for Quality Commitment?	 Yes	No		At this point formal Quality Management Review is not being conducted. It will be initiated in 2024 and followed through at the 2025 Internal Audit for completion. Management is fully committed to Quality as was noticed during the audit for OFIs addressed during audit discussions for several SOPs and MPs for minor edits and non-alignments to current processes.

2024 Internal cGMP Audit Summary for Shankara Products:

Shankara continues to remain committed to cGMP Compliance. Their proactive approach and can-do attitude have helped with their commitment to continuous improvement to support their increasing volumes and their product portfolio. During the pre-audit, it was noted that all employees were enthusiastic and continued to learn, grow and fulfill the expectations of their roles. Several preventive actions were put in place in Shankara's QMS when the CAPAs from 2023 Audit were addressed during the 2024 audit preparation.

Shankara is now FDA registered as required by MOCRA (Modernization of Cosmetic Regulation Act). Shankara wants to grow and remain compliant to the new expectations by FDA for the cosmetic industry. Shankara will very likely be fully audit ready once FDA starts auditing Cosmetic manufacturers, as it is adding additional Quality controls in 2024 such as Annual Management Review. It was heartening to note that the upper management of Shankara is committed to Quality and Compliance and sets the tone for all employees. Several MPs have been updated in 2024 raising the bar for Shankara's QMS for streamlining their production processes.

It must be noted that significant improvements have been made by Shankara in the following areas since the last GMP audit in March 2023:

- Improved MPs
- Production software updates (ongoing)
- ASL Improvements (ongoing)
- Review and Approval of Work Orders in a timely manner
- Backups for most positions to cover vacations and sick leave (ongoing)

The gaps noted as non-conformances and opportunity for improvement are highlighted in the above audit report in bold.

One Non-conformance (NC) observed for cGMP compliance: NC #1: ASL Gaps. See Page 4 of the Audit Report for details.

The 3 OFIs (opportunity for improvement) are being pointed out from this audit.
See:

- Page 4 for OFI #1:
- Page 5 for OFI #2
- Page 8 for OFI #3

Several corrections were completed during the audit such as minor modifications to signs on Production room doors for protective safety gear and appropriate labeling in the warehouse.

Report Summarized by Meena Chettiar, MNQ Consultants on 08/26/24: Minor typo related changes made on 11/13/24 during Management review prep.

Meena Chettiar

Receipt of cGMP Compliance Status report acknowledged by Shankara signed by/on:

Bhushan Deodhar, CEO on 08/26/2024 Ajay Tejasvi, President on 08/26/2024

Bhushan Deodhar

Ajay Tejasvi