

Spectral Service AG

Self-disclosure

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1. Company Details		
Company Name:	Spectral Service AG	
Address:	Street:	Emil-Hoffmann-Str. 33
	Zip code & City:	D-50996 Cologne
	State:	North Rhine Westphalia
	Country:	Germany
	GPS coordinates:	50.86704779485865, 6.991781719799232
VAT Number:	DE 122 805 644	
Facility establishment identifier/DUNS' number:	331474932	
Legal Status of Organisation:	PLC	
Website:	https://www.spectralservice.de/	
Description of Services:	Spectral Service is a non-manufacturing company and provides the following analyses: • Qualitative and quantitative NMR • FT-IR spectroscopy • ESI mass spectrometry • Structure elucidation by NMR & ESI-MS • Pesticide analysis under GLP • Pharmaceutical analysis under GMP • Food analysis, especially lipid and phospholipid analysis by NMR • 5-batch analyses for standardized testing and approval procedures under GLP	
Employees:	• Study Directors (QC): 18 • QA: 7 • Laboratory: 6 • IT: 2 • Others: 12	
The markets where Spectral Service provides its services:	pharmaceuticals, food, cosmetics, and chemical industry	
Date of Incorporation:	1990	
2. Contacts		
Head of test facility & Quality Control	Name:	Dr. Jan Sommer
	Mail:	jan.sommer@spectralservice.de
Head of Quality Assurance	Name:	Karen Gedig
	Mail:	karen.gedig@spectralservice.de
Finance	Name:	Michael Ernst
	Mail:	michael.ernst@spectralservice.de
Customer Service	Phone:	+49 ((0)2236) 96947-0
	Mail:	info@spectralservice.de or phospholipid@spectralservice.de

3. Quality Management and Quality Assurance					
3.1. Quality Assurance and Certification					NOTES
1.	Does Spectral Service have a Quality Assurance System in place?	☒ yes	☐ no	☐ n.a.	
2.	What certifications does Spectral Service currently provide to its customers?	GMP & GLP (https://www.spectralservice.de/en/our-quality-standards/)			
3.	Is Spectral Service ISO certified?	☐ yes	☒ no	☐ n.a.	
4.	Is Spectral Service registered with FDA?	☒ yes	☐ no	☐ n.a.	FEI No. 3008542737
5.	Has Spectral Service been inspected by any regulatory authorities? If yes, please indicate the date of last regulatory inspection.	☒ yes	☐ no	☐ n.a.	- MAGS NRW 14./17.01.2025 (GLP) - District government, Cologne, 13.02.2025 (GMP) - FDA (on-site) 08/09.09.2014
6.	What quality standards does Spectral Service adhere to?	GMP/GLP, 21 CFR parts 210 & 211 and EU guidelines			
3.2. Quality Management System					NOTES
7.	Does Spectral Service have a Quality Management System in place?	☒ yes	☐ no	☐ n.a.	
8.	Are Spectral Service's internal quality audits conducted periodically to review the Quality System?	☒ yes	☐ no	☐ n.a.	Every part of the system is inspected minimum annually
9.	Does Spectral Service have a documented procedure for: (1) Equipment qualification (2) Education and Further Training (3) Quality Assurance - Inspection of Facility and Analytical Tests (4) Management review (5) Procurement of services and equipment (6) Archiving (7) Quality Risk Management (QRM)	☒ yes	☐ no	☐ n.a.	(1) Doc. No. SAA-BAA003 (2) Doc. No. SAA-ABA002 (3) Doc. No. SAA-QSE001 (4) Doc. No. QMH415 Doc. No. SAA-BAA019 (5) Doc. No. QMH406 (6) Doc. No. SAA-ABA006 (7) Doc. No. SAA-BAA014
10.	Does Spectral Service provide access to a Site Master File (SMF) for both employees and clients?	☒ yes	☐ no	☐ n.a.	
11.	Does Spectral Service have a Validation Master Plan (VMP)?	☒ yes	☐ no	☐ n.a.	
12.	Does Spectral Service have a valid Quality Management Handbook (QMH)?	☒ yes	☐ no	☐ n.a.	

3.3. Documentation and Archives					NOTES
13.	Are all documents maintained according to the Good Documentation Practice (GDocP) system?	☒ yes	☐ no	☐ n.a.	
14.	How long is raw data archived?	- Raw data is only archived for analyses under GLP and for electronic measurement raw data and kept for at least 15 years - Raw data under GMP is sent to the customer for archiving (responsibility of the customer),			
15.	How does Spectral Service archive and organize its documents?	Paper-based (GLP) and electronically (GMP)			
16.	How does Spectral Service ensure the security of archived data to prevent unauthorized editing?	- The paper archive is restricted for archivists - Access to the electronic archive is restricted by the IT system's administrator (under GLP for archivists) - Changes to electronic documents are traceable (who, what, when, etc.)			
17.	Are deviations and non-conformances documented and filed?	☒ yes	☐ no	☐ n.a.	
18.	Are the modification, maintenance, archiving, retrieval, and transmission of electronic records conducted in accordance with the requirements outlined in 21 CFR Part 11, Electronic Records; Electronic Signatures?	☒ yes	☐ no	☐ n.a.	
19.	Does Spectral Service maintain a current backup copy of all analytical technique documents, SOPs, notebooks, analytical test records, etc.?	☒ yes	☐ no	☐ n.a.	
3.4. Personnel and Training					NOTES
20.	Are job descriptions available for all employees, and are training records maintained for each employee?	☒ yes	☐ no	☐ n.a.	
21.	Are there general and job-specific training programs for new and existing employees?	☒ yes	☐ no	☐ n.a.	
22.	Is Spectral Service involved in the field of research and development?	☒ yes	☐ no	☐ n.a.	

3.5. HSE (Health, Safety and Environment)					NOTES
23.	Does Spectral Service have a documented procedure for waste disposal?	☒ yes	☐ no	☐ n.a.	Doc. No. SAA-GMR002
24.	Have safety and health protection-related activities and tasks, such as designating a fire protection officer and outlining their responsibilities, been adequately implemented?	☒ yes	☐ no	☐ n.a.	• Fire protection representative • First aider • Safety representative
25.	Are employees provided with hygiene, safety, and health instructions?	☒ yes	☐ no	☐ n.a.	
26.	Is waste disposal overseen by an authorized manager?	☒ yes	☐ no	☐ n.a.	
27.	Has the company been designed to prevent chemical and physical contamination?	☒ yes	☐ no	☐ n.a.	
28.	Does Spectral Service have an adequate emergency response plan?	☒ yes	☐ no	☐ n.a.	
4. Facility and Organization					
4.1. Facility					NOTES
29.	Does Spectral Service have a system in place for Pest Control and Prevention?	☒ yes	☐ no	☐ n.a.	
30.	Does Spectral Service ensure that the air in working rooms is conditioned and filtered? Moreover, are filters routinely inspected and replaced as necessary?	☒ yes	☐ no	☐ n.a.	
31.	How are the cleaning and disinfection processes carried out within the facility?	An external company undertakes the cleaning processes for non-laboratory rooms in the facility, the laboratory is cleaned by the lab technicians			
32.	What access control system is implemented in the facility?	Chip access			
33.	Does the infrastructure of the facility have acceptable/sufficient space for the specialized testing and activities to be carried out?	☒ yes	☐ no	☐ n.a.	Approximate area of the facility: 961 m ²
34.	How many sites does Spectral Service use for providing services?	One			
35.	Does the facility work in shifts?	☐ yes	☒ no	☐ n.a.	

4.2. Samples					NOTES
36.	How are analysis samples labelled, recorded, and stored?	• Labelled with QR-Code • Recorded in our computerized system (Acquisition/Processing of measurement data.) • Stored as indicated in the documentation (temperature controlled)			
37.	What water treatment systems exist, including the one used to obtain purified water in Spectral Service?	• EASY pure RF II D7031 • Softening system WFDK 60 • Water (HPLC grade) is purchased for Lab activities			
38.	How long are samples retained after the completion of testing?	6 weeks			
39.	Does Spectral Service have a system for organizing and managing the acceptance and testing of incoming materials?	☒ yes	☐ no	☐ n.a.	
40.	Are retention samples stored in a quantity sufficient for re-analysis?	☒ yes	☐ no	☐ n.a.	Remaining sample material is stored
41.	Does Spectral Service have a process to establish an expiry or retest date for materials?	☒ yes	☐ no	☐ n.a.	
4.3. Equipment					NOTES
42.	Does Spectral Service have a documented procedure for preventive maintenance, calibration, and re-qualification of equipment to ensure optimal reliability of equipment during operation or use?	☒ yes	☐ no	☐ n.a.	• See specific Device SOPs • Logbooks (to document run time, calibration, maintenance, defects, repair, and release after repair) • Maintenance contracts
4.4. Computer System					NOTES
43.	Does Spectral Service use computer systems for the management of the quality system, quality control, equipments, samples, laboratory, etc.?	☒ yes	☐ no	☐ n.a.	
44.	Does Spectral Service have a documented procedure for the validation and security of computerized or automated data handling systems and software validation?	☒ yes	☐ no	☐ n.a.	• Doc. No. VMP-SSL. • Comply with the provisions of 21 CFR Part 11 or EC GMP Guideline Annex 11
45.	Does Spectral Service provide training to its employees on the use of computerized systems?	☒ yes	☐ no	☐ n.a.	

4.5. Sample Tracking System					NOTES
46.	Does Spectral Service subcontract with an outside company or specialized individuals to perform specific parts of a processes or testing activities, including analysis or transport?	☐ yes	☒ no	☐ n.a.	
47.	Does Spectral Service have an SOP for the proper labelling and storage of reagents, solutions, and samples?	☒ yes	☐ no	☐ n.a.	Doc. No. SAA-GMR001
48.	Does Spectral Service accept materials based on the manufacturer's CoA?	☒ yes	☐ no	☐ n.a.	
49.	Does Spectral Service maintain an Approved Supplier List endorsed by Quality Assurance, specifying supplier details, manufacturing source, and approved materials?	☒ yes	☐ no	☐ n.a.	
5. Quality Control					
5.1. Testing					NOTES
50.	Does Spectral Service regularly conduct tests following general methods in compliance with relevant compendia (e.g., Ph. Eur., USP, JP, OECD), as well as utilizing in-house developed and customer-specific test methods?	☒ yes	☐ no	☐ n.a.	
51.	Can testing be repeated upon the client's request?	☒ yes	☐ no	☐ n.a.	As long as there is sample material
52.	Does Spectral Service have a documented procedure for: (1) Method Validation under GMP (2) Following Up - Tracking System (3) Handling of Test Items	☒ yes	☐ no	☐ n.a.	(1) Doc. No. SAA-BAA015 (2) Doc. No. SAA-BAA005 (3) Doc. No. SAA-PRG001
53.	Is System Suitability Testing a part of Spectral Service's routine analytical methods?	☒ yes	☐ no	☐ n.a.	
54.	Does Spectral Service provide stability studies for samples?	☒ yes	☐ no	☐ n.a.	Only under GLP (not under GMP)
55.	Are the testing procedures at Spectral Service validated according to ICH guidelines?	☒ yes	☐ no	☐ n.a.	
56.	Are pharmacopoeia methods and methods received from customers verified or validated according to Spectral Service SOPs?	☒ yes	☐ no	☐ n.a.	Depends on customer's requirements
57.	How does spectral service ensure that mixing-up of samples and/or methods does not occur?	- Every sample is assigned a unique number composed of three letters, an internal order number, and a sample index; all processing is carried out using this number - Follow the instructions in the SOP (Doc. No. SAA-PRG001)			

5.2. Reporting				NOTES
58.	How are the final results reported to customers, and what method is utilized for the transmission of reports?	Electronically signed report or Certificate of Analysis (CoA) transmitted via E-Mail using FTAPI if desired; GLP paper based using a courier service		
59.	Does Spectral Service have a documented procedure for sample registration or order processing?	☒ yes	☐ no	☐ n.a. Doc. No. SAA-PRG001
60.	Does Spectral Service have a documented SOP for reporting results /CoA to the client organization?	☒ yes	☐ no	☐ n.a. Doc. No. SAA-ABA005 and SAA-ABA008
5.3. Change Control, Deviation, Complaint, CAPA and OOS				NOTES
61.	Does Spectral Service have a documented procedure for Change Control?	☒ yes	☐ no	☐ n.a. Doc. No. SAA-BAA002
62.	Does Spectral Service have a documented procedure for handling of Deviations?	☒ yes	☐ no	☐ n.a. Doc. No. SAA-BAA017
63.	Does Spectral Service have a documented procedure for handling of OOS (Out of Specification)?	☒ yes	☐ no	☐ n.a. Doc. No. SAA-BAA004
64.	How long will Spectral Service need to inform customers about an OOS?	Within one workday		
65.	Are amendments appropriately dated and signed when changes in data are observed, and is the original data readily accessible?	☒ yes	☐ no	☐ n.a.
66.	Are deviations and non-conformances investigated?	☒ yes	☐ no	☐ n.a.
67.	Does Spectral Service inform customers of major changes in analytical procedures, laboratory site, etc.?	☒ yes	☐ no	☐ n.a.
68.	Does Spectral Service have a documented procedure for handling of Complaints?	☒ yes	☐ no	☐ n.a. Doc. No. SAA-BAA017
69.	Does Spectral Service annually review and track complaints, and if so, who handles them?	☒ yes	☐ no	☐ n.a. Responsibility of QA
70.	Who has the authority to release analysis and reports/CoA?	Reports released by study director and reviewed by QA (double check)		
71.	Does Spectral Service provide training to its employees on a CAPA (Corrective and Preventive Actions) system to ensure that staff learn from mistakes and prevent the recurrence of similar mistakes?	☒ yes	☐ no	☐ n.a.
72.	Does Spectral Service have a documented SOP for CAPA?	☒ yes	☐ no	☐ n.a. Doc. No. SAA-BAA017