

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	
Commercial Register Number		HRB 70325	
Entry Year Commercial Register		2010	
Facility establishment identifier/DUNS' number:		331474932	
Bank Details	Account Holder	Spectral Service AG	
	IBAN	DE34 3705 0299 0000 3839 21	DE48 3708 0040 0388 8198 00
	BIC / SWIFT Code	COKSDE33	DRESDEFF370
	Name of Bank	Kreissparkasse Köln	Commerzbank Köln
Legal Status of Organisation:		PLC	
Website:		https://www.spectralservice.de/en/	
Description of Services:		<p>Spectral Service is a non-manufacturing company and provides the following analyses:</p> <ul style="list-style-type: none"> • 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:		<ul style="list-style-type: none"> • Study Directors (QC): 17 • QA: 7 • Laboratory: 5 • 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	<input type="checkbox"/> n.a.	
4.	Is Spectral Service registered with FDA?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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.	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	<ul style="list-style-type: none"> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
8.	Are Spectral Service's internal quality audits conducted periodically to review the Quality System?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	Every part of the system is inspected at a 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)	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
11.	Does Spectral Service have a Validation Master Plan (VMP)?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
12.	Does Spectral Service have a valid Quality Management Handbook (QMH)?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	

3.3. Documentation and Archives					NOTES
13.	Are all documents maintained according to the Good Documentation Practice (GDocP) system?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
14.	How long is raw data archived?	<ul style="list-style-type: none"> Raw data is only archived for analyses under GLP and for electronic measurement raw data is 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?	<ul style="list-style-type: none"> The paper archive is restricted to 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
19.	Does Spectral Service maintain a current backup copy of all analytical technique documents, SOPs, notebooks, analytical test records, etc.?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
3.4. Personnel and Training					NOTES
20.	Are job descriptions available for all employees, and are training records maintained for each employee?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
21.	Are there general and job-specific training programs for new and existing employees?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
22.	Is Spectral Service involved in the field of research and development?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	

3.5. HSE (Health, Safety and Environment)					NOTES
23.	Does Spectral Service have a documented procedure for waste disposal?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	<ul style="list-style-type: none"> • Fire protection representative • First aider • Safety representative
25.	Are employees provided with hygiene, safety, and health instructions?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
26.	Is waste disposal overseen by an authorized manager?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
27.	Has the company been designed to prevent chemical and physical contamination?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
28.	Does Spectral Service have an adequate emergency response plan?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
4. Facility and Organization					
4.1. Facility					NOTES
29.	Does Spectral Service have a system in place for Pest Control and Prevention?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	<input type="checkbox"/> n.a.	

4.2. Samples				NOTES
36.	How are analysis samples labelled, recorded, and stored?	<ul style="list-style-type: none"> • 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?	<ul style="list-style-type: none"> • 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.
40.	Are retention samples stored in a quantity sufficient for re-analysis?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.
41.	Does Spectral Service have a process to establish an expiry or retest date for materials?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.
		<ul style="list-style-type: none"> • 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, equipment, samples, laboratory, etc.?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.
		<ul style="list-style-type: none"> • 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input type="checkbox"/> yes	<input checked="" type="checkbox"/> no	<input type="checkbox"/> n.a.	
47.	Does Spectral Service have an SOP for the proper labelling and storage of reagents, solutions, and samples?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	Doc. No. SAA-GMR001
48.	Does Spectral Service accept materials based on the manufacturer's CoA?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
49.	Does Spectral Service maintain an Approved Supplier List endorsed by Quality Assurance, specifying supplier details, manufacturing source, and approved materials?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
51.	Can testing be repeated upon the client's request?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	If 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	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
54.	Does Spectral Service provide stability studies for samples?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	Only under GLP (not under GMP)
55.	Are the testing procedures at Spectral Service validated according to ICH guidelines?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	
56.	Are pharmacopoeia methods and methods received from customers verified or validated according to Spectral Service SOPs?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.	Depends on customer's requirements
57.	How does spectral service ensure that mixing-up of samples and/or methods does not occur?	<ul style="list-style-type: none"> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a. Doc. No. SAA-PRG001
60.	Does Spectral Service have a documented SOP for reporting results /CoA to the client organization?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a. Doc. No. SAA-BAA002
62.	Does Spectral Service have a documented procedure for handling of Deviations?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a. Doc. No. SAA-BAA017
63.	Does Spectral Service have a documented procedure for handling of OOS (Out of Specification)?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.
66.	Are deviations and non-conformances investigated?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.
67.	Does Spectral Service inform customers of major changes in analytical procedures, laboratory site, etc.?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.
68.	Does Spectral Service have a documented procedure for handling Complaints?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a. Doc. No. SAA-BAA017
69.	Does Spectral Service annually review and track Complaints, and if so, who handles them?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> 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?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a.
72.	Does Spectral Service have a documented SOP for CAPA?	<input checked="" type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> n.a. Doc. No. SAA-BAA017