Fragebogen zur Eignungsprüfung

	Bezeichnung	Antwort	Kriteriengewichtung
1	**Zulassung Angebote**		
1.1	**The following suitability criteria must be submitted in full with the offer. Incomplete documents may lead to exclusion from the procedure.If there are differences between the German wording and the Englisch wording, than the content of the German wording always applies.**		
F 1.1.1	**Subcontractors** In the event that subcontractors are used, they must be named in the following text field. Indicate whether and to what percentage extent you use the capacities of subcontractors according to § 34 UVgO or §47 VGV. The subcontractors must necessarily attach the following self-declarations. - Self-declaration regarding the absence of exclusion criteria § 123 und § 124 GWB - Selfdeclaration (EU) Nr. 833/2014 Furthermore, it must be confirmed that they will be available if the order is placed; their share in the scope of the contractual object must be stated. IF YOU DO NOT USE SUBCONTRACTORS, PLEAS WRITE THE WORD "NO" INTO THIS FIELD.		
F 1.1.2	**Profile of your company** Representation of the company at least the following information: founding year, number of employees, what is produced / what services are provided -> Please provide all information in text form. NO links or Pictures.		
F 1.1.3	**Turnover** Turnover for years 2021, 2022, 2023		

	Bezeichnung	Antwort	Kriteriengewichtung
F 1.1.4	**Self-declaration regarding the absence of exclusion criteria** *** NOTE *** THE FILE ("Self-declaration_absence_of_exclusion_criteria"), WHICH YOU MUST UPLOAD AS PROOF, IS TO BE SPECIFIED IN THE TEXT FIELD		
F 1.1.5	**Self-declaration (EU) Nr. 833/2014** *** NOTE *** THE FILE ("Self-declaration_Russia_sanctions_(EU)_Nr.8332014"), WHICH YOU MUST UPLOAD AS PROOF, IS TO BE SPECIFIED IN THE TEXT FIELD		
F 1.1.6	**Proof of conduct of service according to ICH-GCP-guideline, especially ICH E6 (R2) und E8 and CTR (EU) No. 536/2014 and Directive 2001/83/EC**		
F 1.1.7	**Long time archiving process according to ICH-GCP for at least 25 years** e.g. proof of SOP		
F 1.1.8	**Fulfilment of security requirements for the processing of personal data** e.g. proof of certification according to ISO 27001, ISO 22331		
F 1.1.9	**Proof of GCP-compliant quality management system** e.g. ISO 9001 certified, evidence of standard operating procedures (SOPs), certificates, organizational charts, SOP lists, already audited by the client		
F 1.1.10	**Compliance statement** o ICH Q10: Pharmaceutical Quality System o GDPR data processing o Volume 4 EU GMP guidelines and its Annexes (Annex 11, 13 and 16)		

	Bezeichnung	Antwort	Kriteriengewichtung
	o EU Commission Directive 2017/1572 and EU Commission Delegated Regulation 2017/1569 o EU GDP Medicinal Products for Human Use (2013/C 343/01) o ICH Q9: Quality Risk Management		
F 1.1.11	**Processes for computer system validation** e.g. based on GAMP5, FDA CRF Part 11 or EU GMP Annex 11: Computerized Systems		
F 1.1.12	**Business continuity processes** e.g. proof of SOP		
F 1.1.13	**Manufacturing license for oral liquid solution**		
F 1.1.14	**GMP Certificate**		
F 1.1.15	**Depot in EU and sufficient storage capacity**		
F 1.1.16	**Storage and documentation according to ICH-GCP**		

	Bezeichnung	Antwort	Kriteriengewichtung
F 1.1.17	**Experience of the manufacture of oxygen sensitive products**		
F 1.1.18	**Experience in manufacturing of photo-sensitive products under yellow light**		
F 1.1.19	**Capability of nitrogen purging throughout the manufacturing mixing steps**		
F 1.1.20	**Import license according to § 72 AMG according to German Drug Law (AMG)**		
F 1.1.21	**Sustainability** e.g. provision of sustainability concept or certificates		