

QUALITY AGREEMENT

1. PURPOSE:

20.25.05

This agreement specifies to agree the testing of Samples using relevant technique given by the Contract Acceptor in line with Good Manufacturing Practices/Good Laboratory Practices and respective regulations/guidelines.

This agreement is between the M/s AVASYA LABS PRIVATE LIMITED, (hereafter known as CG) and M/S J. HEYROVSKÝ INSTITUTE OF PHYSICAL CHEMISTRY OF THE CAS, V. V. I. (hereafter known as CA).

The purpose of this document is to establish Agreement between the following parties:

<u>CONTRACT GIVER (CG)</u> (AVASYA LABS PVT. LTD.,)	CONTRACT ACCEPTOR (CA) (J. Heyrovský Institute of Physical Chemistry of the CAS, v. v. i.)
Address: Plot No. 11, 47 & 48,	Address: Dolejškova 2155/3
Ground Floor, Subhash Chandrabose Nagar,	182 23 Prague 8
New Hafeezpet,	Czech Republic
Hyderabad-500049,	
Telangana, India.	Telephone:
Telephone:	

2. CONFIDENTIALITY:

Both parties undertake to maintain strict confidentiality, which shall also apply after the Agreement has ended. Neither party is entitled to use the knowledge of the other disclosed to it under this Agreement, after the end of the Agreement or without the consent of the other party. Excluded are disclosures of information necessary for Regulatory Authorities during inspections.

Each Party wishes to disclose to other Party Confidential Information in relation to and only for Purpose. Each Party wishes to ensure that other Party maintains confidentiality of its Confidential Information. In consideration of benefits to Parties of disclosure of Confidential Information, Parties have agreed to comply with following terms in connection with use and disclosure of Confidential Information.

Recipient shall keep Disclosing Party's Confidential Information confidential and, except with prior written consent of Disclosing Party, shall, and shall procure that its Representatives shall:



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- not use or exploit Confidential Information in any way except for Purpose;
- not disclose or make available Confidential Information in whole or in part to any third party, except as expressly permitted by this Agreement.
- not copy, reduce to writing or otherwise record Confidential Information except as strictly
 necessary for Purpose (and any such copies, reductions to writing and records shall be property
 of Disclosing Party);
- keep confidential and not reveal to any person, firm or company (other than Disclosing Parties) fact that discussions or negotiations are taking place or have taken place between Disclosing Party and Recipient

3. **RESPONSIBILITIES:**

This document defines the individual responsibilities of the Contract Giver and the Contract Acceptor. Responsibility for each activity is assigned to either the Contract Giver (CG) or the Contract Acceptor (CA) in the appropriate tick box. If any element of the checklist does not apply, it must be clearly crossed through (put dash '-' or 'NA') and do not left blank.

These responsibilities will not be varied by either party without the mutual consent and the inclusion of the revised details within this document and approval of the same by both Parties.

Both Parties are responsible for meeting the Terms of the Agreement and for compliance with all regulatory requirements relating to the operations for which each Party is responsible under this agreement.

Individual responsibilities are detailed as follows, but both Parties should recognize that many responsibilities involve discussion, mutual cooperation and agreement so that the Product(s) quality, safety, efficacy and regulatory compliance are assured.

Agreement is effective from last signature date and valid up to 3 years.

Responsibility for each activity is assigned to either CG or CA (CG: Avasya Labs Pvt. Ltd. Or CA: J. Heyrovský Institute of Physical Chemistry of the CAS, v. v. i.) in the appropriate tick box. (Based on mutual agreement Responsibilities can be varied.)

S.No.	RESPONSIBILITIES	CA	CG
1	Confidentiality of the Agreement / Statement	Ń	
2	Working Procedures and analytical instructions for testing of sample	V	
3	Instrument Qualification, Calibrations and usage records	Ń	
4	Trained & qualified Analyst shall perform the analysis	Ň	
5	Maintain Reference number for tracking purpose	N	
6	Prepare and provide complete data along with results of analysis to CG	Ń	
7	Carry out appropriate safety assessments for the tests undertaken	\checkmark	
8	Not to supply Product or to disclose information regarding Product to any individual or organization without the written permission of the CG.	V	
9	Provision of information to the CG of any matters found during a regulatory	N	

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S.No.	RESPONSIBILITIES	CA	CG
	inspection that directly effect the ability of the CA to carry out their duties in accordance with this agreement		
10	Notification to the CG of any Deviation/Changes/CAPA which relates to matters for which the CG has responsibility.	\checkmark	
11	CA will notify the CG if any Out of specification results observed.	N	
12	In case, out of specification results observed for sample, conduct the Laboratory investigation as per CG procedure	\checkmark	
13	Provide support in the investigation and closure as agreed	V	
14	Disposal of waste Product and materials at the site of testing in accordance with local regulations and in a manner, it assures that the waste and all materials are rendered unusable and unrecognizable.	\checkmark	
15	Retain samples for 30 days from results reported or return to CG as pr mutually agreed.	\checkmark	
16	Retention of all GMP documents and records relating to the activities carried out by the CA which may the quality, safety, efficacy of Product.	\checkmark	
17	Disposal of records as per CA archival procedure and inform CG before dispose	X	

CONTACT DETAILS

	J. Heyrovský Institute of Physical Chemistry of the CAS, v. v. i. (Contact Acceptor)	Avasya Labs Pvt. Ltd. (Contact Giver)
Name:	Martin Hof	
Designation:	Prof., Dr. rer. nat. DSc.	Manager
Department:	Director	Manager Quality Assurance
Tel:		
e-mail:	director@jh-inst.cas.cz	U
Sign & Date	prof. Digitálně podepsal prof. Martin Martin Hof Datum: 2023.03.23 Hof 11:04:23 +01'00'	23/03/2023 AFUABS P

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