Certificate of Analysis

ExViGel-HLFO (Human Liver Fibrosis Origin)

FOR RESEARCH USE ONLY. Not intended for human or animal diagnostic or therapeutic uses. Human-derived products must be treated as potential pathogens. Users need to wear personal protective equipment during work.

Catalog number: HLFO

Batch numbers: HLFO 2.1.1

1. Information about donor

Batch number	Sex	Ethnicity	Age	Tissue origin	Pathology or Cause of death
STS13-115	Male	Caucasian	56	Liver Fibrosis	Liver Fibrosis
STS13-116	Female	Caucasian	48	Liver Fibrosis	Liver Fibrosis
STS13-117	Male	Caucasian	69	Liver Fibrosis	Liver Fibrosis

Biological materials were collected from certified clinical hospitals. Clinical site provided ethical committee approval and conducted the collection in accordance with the Directive 2004/23/EC of the European Parliament

2. Viral RNA Detection by qPCR

Virus	Specification	Result	
Hepatitis B	Negative	Positive ◯	Negative **X**
Hepatitis C		Positive ◯	Negative **X**
HIV-1 and HIV-2		Positive ◯	Negative **X**

3. Product Information

Process	Human extracellular matrix was isolated and frozen by the patented method. No digestion or protein cleavage was applied.
Biosafety level	Human-sourced products should be handled at the Biological Safety Level 2 (BSL 2)
Production Date	10/09/2024
Last Control Date	21/09/2024
Packaging	5 mL suspension in a glass vial

4. Quality Control after Thawing

Criteria	Specification	Result	Conclusion	
Protein concentration	≥ 10mg/ml	15.3 mg/ml	Yes **X**	No ◯
Gelling	Gelation at +37 °C after 1h	Positive	Yes **X**	No ◯
Critical gelation concentration	≥ 5 mg/ml	8 mg/ml	Yes **X**	No ◯
GuaHCl concentration	< 1 x 10^{-3} M	< 1 x 10^{-3} M	Yes **X**	No ◯
Surfactants concentration	Non detected	Non detected	Yes **X**	No ◯
Microbial sterility	No microbial growth detectable	Undetectable	Yes **X**	No ◯

5. ELISA Measured Protein Concentration

Protein	Concentration
Elastin, mg/g	0,162
Laminin, mg/g	2,375
Fibronectin, mg/g	2,212
Tenascin, mg/g	0,547
TGFA, ug/g	0,325
EGF, ug/g	0,0042
IGF1, ug/g	0,0023
TGFB-1, ug/g	18,44
Collagen Type-I, mg/g	6,785
Collagen Type-II, mg/g	0,467
Collagen Type-III, mg/g	2.102
Collagen Type-IV, mg/g	0,573
Collagen Type-V, mg/g	0,264
Collagen Type-VI, mg/g	0,155

6. AFM-based Measurements

Measurement	Result
AFM-based colloid size at sol state (nm)	20.5
AFM-based collagen fibre formation (Yes/No)	Yes
AFM-based collagen fiber diameter (nm)	63.4
Elasticity Modulus at Maximum Concentration (kPa)	0,873
Elasticity Modulus at Maximum Gelation Dilution (kPa)	0,65

7. Biocompatibility

Experiment	Results
Primary Human Hepatocytes (reference plateable batch) confluency	30%
HepG2 doubling time	38 hours
Weight loss in BALB/c mouse (relative to Matrigel), 14 days exposure	TBD

8. Visa for Batch Release

Name	Signature	Date
Vladyslav Moseiko		20/09/2024