Certificate of Analysis

Human Cryopreserved Hepatocytes Grade P, Qualified for Plateable Assays

FOR RESEARCH USE ONLY. Not intended for human or animal diagnostic or therapeutic uses. HUMAN CRYOPRESERVED SUSPENSION HEPATOCYTES are not recommended for cultivation. Human primary cells must be treated as potential pathogens. Users need to wear personal protective equipment during work. DO NOT USE DRY ICE DURING WORK, STORAGE, OR TRANSPORTATION.

Catalog number: HEPP725

Batch numbers: HEP187725

1. Information about donor

Age	Sex	Ethnicity	Pathology or Cause of death	Patient information					
				Diabetes	Heart disease	High blood pressure	Smoking	Alcoholism	Medication
18	Male	Caucasian	Blunt head trauma	No	No	No	No	No	No

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 hepatocytes were isolated and frozen by standard methods.
Biosafety level	Human-sourced products should be handled at the Biological Safety Level 2 (BSL 2)
Date of Production	27/09/2023
Last QC Date	29/09/2023
Packaging	0.5 mL suspension in the cryovial with a minimum of 8 x 10^6 viable cells.

4. Cell Quality Control after Thawing

Criteria	Specification	Result	Conclusion	
Post-thaw viability	≥ 80 %	91 %	Yes **X**	No ◯
Number of viable cells per vial	≥ 8 x 10^6	9.5 x 10^6	Yes **X**	No ◯
Optimal Percoll concentration	25-28 %	25 %	Yes **X**	No ◯
BCA Test	250 µg/cm^2	270 µg/cm^2	Yes **X**	No ◯
Cell confluence in 20-24 h of cultivation on collagen I coated plate	≥ 75 %	92 %	Yes **X**	No ◯
Microbial sterility	No microbial growth detectable	Undetectable	Yes **X**	No ◯

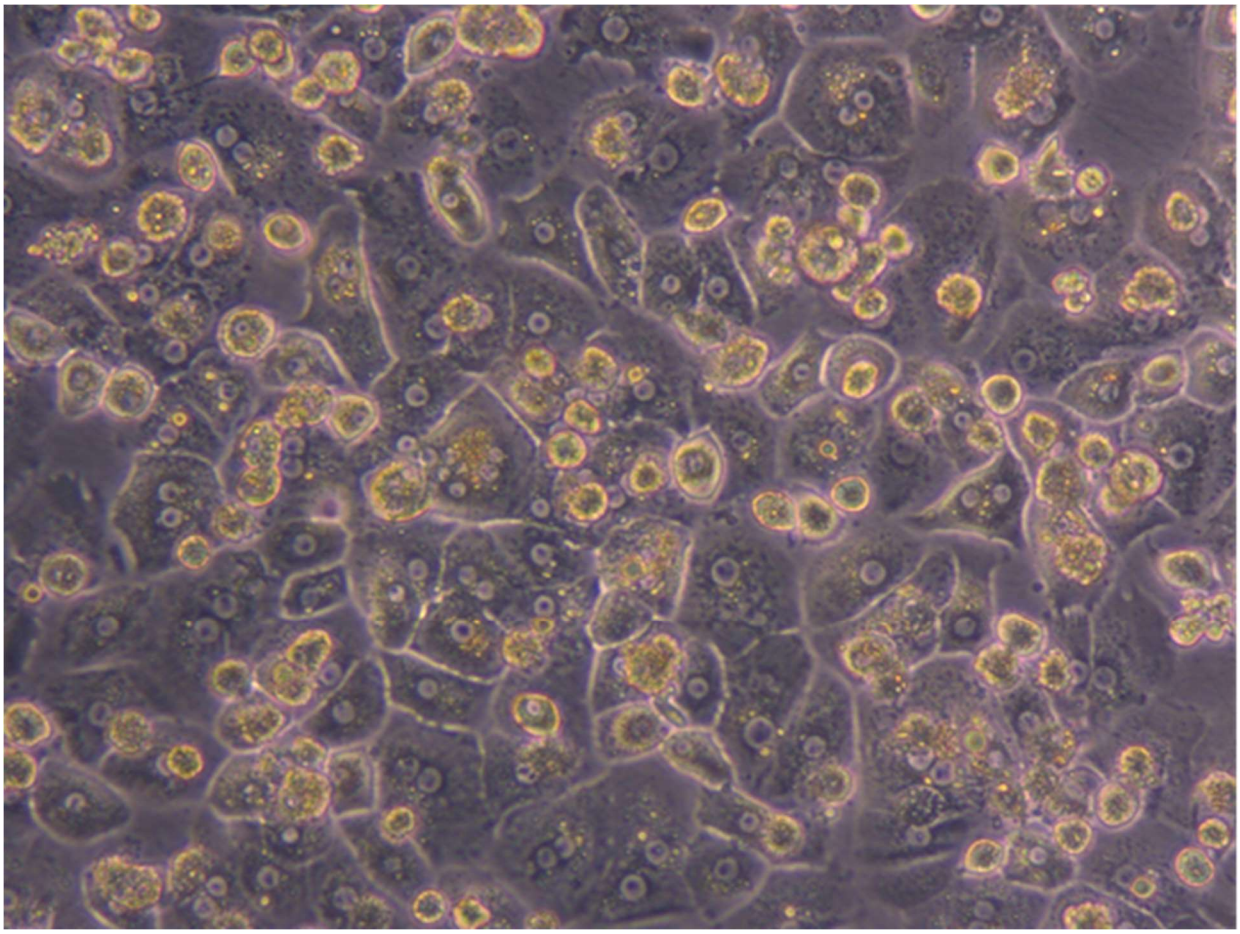
5. Metabolic Characterization

Substrate	Intrinsic Clearance (µL/min/10^6 cells)	Enzyme Responsible for Metabolism
Verapamil	6.7	CYP2C8, CYP3A4, CYP3A5, CYP1A2
Diclofenac	28.6	CYP2C9, UGT2B7, UGT1A9
7-Hydroxycoumarin	65.4	CYP3A4, CYP2B6, CYP2C9, CYP2C19, UGT2B17
Imipramine	4.1	CYP2D6, CYP1A2, CYP2C19, CYP3A, UGT1A4

6. Enzyme Induction Assay

Enzyme	Inducer	Result (mRNA Relative Fold)	Conclusion	
CYP1A2	Omeprazole (50 µM)	468.5	Yes **X**	No ◯
CYP2B6	Phenobarbital (1000 µM)	13.6	Yes **X**	No ◯
CYP3A	Rifampicin (20 µM)	39.8	Yes **X**	No ◯

7. Microphotograph



24-hours of cultivation, 200x magnification

Magnification	x200
Cell Seeding Density	0,5 mln cells/well
Well Format	24-well collagen-coated culture plate
Cultivations Condition	Williams Medium E + HepExtend + 1% Penicillin/Streptomycin

8. Cell Storage

Delivery	In liquid nitrogen, ≤ -150^{0}C
Storage temperature	In vapour of liquid nitrogen, ≤ -150^{0}C up to 5 years

9. Visa for Batch Release

Name	Signature	Date
Tetiana Papurina		03/10/2023