



Kitazato Corporation

<http://www.kitazato.co.jp/>

PRODUCT: Hypure® Oil Heavy

LOT#: E1002

EXPIRY DATE : 2026/04/30

Year/Month/Day

REF: 96011

CODE: MOHVD-100P

APPROVED BY :  Kazumi Shibata  
Quality Control

DATE : 2024 / 11 / 7

Year/Month/Day

## CERTIFICATE OF ANALYSIS

**Indication for Use:** Hypure® Oil is intended to be used as an overlay for culture of embryos, oocytes and sperm in ART procedures.

**Storage:** Store between 15-25°C.

**Caution:** Federal law restricts this device to sale by or on the order of a physician or practitioner trained in its use.

The product has been manufactured by Kitazato Corporation in conformity with requirements of ISO13485 Quality management system. The quality of products was tested and evaluated by quality control procedures.

ASSAY	SPECIFICATION	RESULT
Color	Clear, Particle Free	Clear, Particle Free
Endotoxin <sup>1</sup>	< 0.1 EU/ml	<0.1 EU/ml
Sterility <sup>2</sup>	No microbial Growth	No growth
MEA(One Cell) <sup>3</sup>		
- Control	≥ 80%	100 %
- This Lot MEA 1	≥ 80%	95.24 %
- This Lot MEA 2	≥ 80%	100 %
POV	<0.1 mEq/Kg	<0.06 mEq/Kg

<sup>1</sup> Bacteria Endotoxins Test, Photometric Techniques in accordance with the USP, EP and JP

<sup>2</sup> Sterility Tests, Direct Inoculation in accordance with the USP, EP and JP

<sup>3</sup> One cell mouse embryo testing is performed using fresh mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 120 hours in culture medium.