



SYNBIOS® DISPERASE ENZYME

GENERAL INFORMATION ON USE

Disperase is made up in SYNBIOS® Flushing medium.
Disperase is a cell dissociation enzyme of microbial origin.

SYNBIOS® Flushing medium (HEPES- buffered medium used is synthetic and devoid of added proteins). The product is ready for use. SYNBIOS® Disperase medium is used to denude or strip the oocyte of its cumulus and corona cells. Disperase digests the bonds between the cumulus cells, which makes it easier to disperse and remove the cumulus cells mechanically

MATERIALS SUPPLIED

10ml of SYNBIOS® DISPERASE ENZYME. (Ref: DE10010. SYN). This product is devoid of HSA.

MATERIALS REQUIRED BUT NOT SUPPLIED

Test tubes & culture dishes; Oocyte and embryo handling pipettes; Laminar flow/Biological hoods, Stereo & Inverted Microscopes; Incubators, and other

ART Lab equipment. Others include: SYNBIOS® culture, sperm; Gamete, Flush and PVP media.

SPECIFICATIONS AND QUALITY CONTROL

SYNBIOS® DISPERASE ENZYME medium is manufactured according to these specifications:

pH: 7.30 – 7.60 (release criteria under air)

Osmolality: 270 – 290 mOsm/kg

Endotoxin: < 1.00 EU/ml

Sterility: Sterile

Mouse-embryo test: ≥ 80% blastocysts after 120 hours culture (exposure at zygote stage)

Use of Ph Eur or USP grade products if applicable

A certificate of analysis and MSDS are available upon request

STORAGE AND CONSERVATION

SYNBIOS® DISPERASE ENZYME medium is stable after transport (max. 5 days) at elevated temperature (≤ 37°C). Store SYNBIOS® DISPERASE ENZYME medium between 2-8°C. Do not freeze before use. Keep the product in original packaging and shield from light/sun. The product can be used for 7 days after opening when sterile conditions are maintained and between 2-8°C. Do not use after expiry date. Content cannot be re-sterilized after opening.

ADVANTAGE: Disperase may not harbour harmful prions and viruses because it is not of animal origin.

CAUTION

SYNBIOS® DISPERASE ENZYME exposed to the elements or above 8°C for >8 hours may be unfit for use for human ART treatment due to possible formation of toxic free radicals and products of putrefaction. Do not use if product appears cloudy.

DISCLAIMER:

This product is manufactured in compliance with the GMP quality standards. Every effort has been taken to ensure quality of the product. We have no control over the products during transport. Shippers are aware of cold-chain protocol. Product could be damaged for any reason during transport. End users must ensure products received are in good condition by internal QC/QA procedures prior to use.

WARNINGS AND PRECAUTIONS

Handle all specimens as if capable of transmitting disease. Always wear protective clothing when handling specimens. The above media do not contain antibiotics, always work under strict hygienic conditions (e.g. LAF-bench ISO Class 5) to avoid contamination. Don't use media if liquid is cloudy. Disperase is a novel experimental product meant for research only at the present moment. The survival and motility of sperm held in Disperase medium was for 72hrs statistically identical to that held in control medium. Development of embryos cultured with Disperase was not affected. **Disperase medium is not intended for human application until further notice.**

MICROBE SOURCED DISPERASE ENZYME

The Disperase enzyme used in this product is derived from microbial cultures.

INSTRUCTIONS FOR USE

1. All procedures should be performed aseptically.
2. Warm SYNBIOS® DISPERASE ENZYME to 37°C.
3. Prepare a dish containing 1 droplet of SYNBIOS® DISPERASE ENZYME medium (100 µL) and 3-5 droplets (100µL) of SYNBIOS® Flushing or gamete medium for oocyte washing (all under light paraffin oil e.g. SYNBIOS® Mineral Oil).
4. Wash oocytes free of blood. Snip off blood clots using 2 sterile 26g needles fitted to 2-3ml syringes.
5. Place oocytes using oocyte handling pipet in SYNBIOS® DISPERASE ENZYME droplet (up to 5 oocytes maximum) for about 30 seconds.
6. Gently pipet oocytes repeatedly with same pipet.
7. Using denuding pipets (145 microns) transfer the partially denuded oocytes in the first washing droplet.
8. Remove the cumulus and corona cells by pipetting the oocytes repeatedly with a 130- 145 micron denuding pipet until the oocytes are fully stripped of cells..
9. Use remaining droplets to wash the denuded oocytes.
10. Transfer the oocytes to equilibrated and warmed SYNBIOS® EMBRYO CULTURE MEDIUM and incubate in a CO₂ incubator before ICSI as per standard protocol.

NOTE: Do not incubate in a CO₂ incubator. Disperse **SYNBIOS[®]** medium is HEPES-buffered. Incubation in a CO₂ incubator could lower the pH below 7, which must be avoided.

Good Laboratory Practices

ART Lab personnel are urged to adhere to Good Laboratory Practices (GLP) for optimizing the treatment outcome. Dishes must not be out of incubator for more than 3 mins at any one time.

Note: This product is classified as a medical device. US Federal Law restricts its sale by or on order of a physician (Rx only).

Custom-produced under GMP quality standards

For ANDROCRYOGENICS, Malaysia

www.synbiosmedia.com

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SYNBIOS[®] DISPERASE

20 Years of Research

Ensures Optimal Performance

SYNBIOS[®] MEDIA
Safety. Performance. Innovation

GMP-Manufactured

DISPERASE for denuding oocytes

Ref: 10 mL DE10010.SYN

SYNBIOS[®] DISPERASE is sterilized by sterile filtration.