

QUALITY ASSURANCE CERTIFICATE



PureSperm® 100

Colloidal stock suspension optimised for discontinuous density gradient separation of human sperm.

Containing: 100 mL

Catalogue no: PS100-100

Batch:
100PS100UJ08

Production date:
08 October, 2014

Expiry date:
07 October, 2016

We certify that this product was manufactured with pharmaceutical quality (ISO 13485) according to the requirements in Annex I in the MDD 93/42/EEC directive. The quality of this particular batch was tested and evaluated objectively by stringent, quality control procedures.

Quality Control procedures:

Accepted values:

Test results:

Physical analyses:

pH at room temperature in air

7.4-7.8

Comply

Osmolality (mOsm)

300-310

Comply

Sterility and toxin analyses:

Microbiological growth control

No growth

Comply

Endotoxin transfer during treatment,
quantitative LAL assay (EU/mL)

<1.0

Comply

Biological analyses:

Human sperm survival after 18 hrs

>70 %

Comply

Date of release: 21 November, 2014

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C.E.O.

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