

QUALITY ASSURANCE CERTIFICATE



PureSperm[®] 100

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

Containing: 250 mL

Catalogue no: PS100-250

Batch:
250PS100UI30

Production date:
30 September, 2014

Expiry date:
29 September, 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) | < 1.00 | Comply |

Biological analyses:

| | | |
|-----------------------------------|-------|--------|
| Human sperm survival after 18 hrs | >70 % | Comply |
|-----------------------------------|-------|--------|

Date of release: 29 October, 2014

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C.E.O.

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