

QUALITY ASSURANCE CERTIFICATE

PureSperm[®] Wash

Optimised for washing the sperm pellet recovered from a PureSperm[®] density gradient separation, for use in the swim-up method and extending semen or sperm pellet for use in IUI.

Containing: 100 mL

Catalogue no: PSW-100

Batch:
I00PSWUF26

Production date:
26 June, 2014

Expiry date:
25 June, 2015

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

7.3-8.5

Comply

Osmolality (mOsm)

290-300

Comply

Sterility and toxin analyses:

Microbiological growth control

No growth

Comply

Endotoxins, quantitative LAL assay (EU/mL)

< 1.00

Comply

Biological analyses:

Human sperm survival after 18 hrs

>70 %

Comply

Date of release: 10 September, 2014

This document is electronically generated and does not bear a signature.

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C.E.O.

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