

QUALITY ASSURANCE CERTIFICATE



PureSperm® 100

Stable colloid/isotonic salt solution for preparation of density gradient used to separate human sperm.

Containing: 250 mL

Catalogue no: PS100-250

Batch:
250PS100YI13

Production date:
13 September, 2018

Expiry date:
12 September, 2020

We certify that this product was manufactured according to set directives for medical devices. 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
Osmolality (mOsm)

7.4-7.8
300-310

Comply
Comply

Sterility and toxin analyses:

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

No growth
< 1.00

Comply
Comply

Biological analyses:

Human sperm survival after 18 hrs

>70 %

Comply

Date of release: 23 October, 2018

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C.E.O.

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