

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:
250PS100XK21

Production date:
21 November, 2017

Expiry date:
20 November, 2019

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:

<i>pH at room temperature in air</i>	<i>7.4-7.8</i>	Comply
<i>Osmolality (mOsm)</i>	<i>300-310</i>	Comply

Sterility and toxin analyses:

<i>Microbiological growth control</i>	<i>No growth</i>	Comply
<i>Endotoxin transfer during treatment, quantitative LAL assay (EU/mL)</i>	<i>< 1.00</i>	Comply

Biological analyses:

<i>Human sperm survival after 18 hrs</i>	<i>>70 %</i>	Comply
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C.E.O.

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