

QUALITY ASSURANCE CERTIFICATE



PureSperm® 40/80

For separation of human sperm with density centrifugation

Containing: 2 x 20 mL

Catalogue no: PSK-020

Batch:

020PS40ZE02

020PS80ZE03

Production date:

02 May, 2019

03 May, 2019

Expiry date:

01 May, 2021

02 May, 2021

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

PureSperm® 40

PureSperm® 80

Physical analyses:

pH at room temperature and in air

7.4–7.8

Comply

Comply

Osmolality (mOsm)

300-310

Comply

Comply

Sterility and toxin analyses:

Microbiological growth control

No growth

Comply

Comply

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

< 1.00

Comply

Comply

Biological analyses:

Sperm survival 18 hrs after density-gradient preparation

>70%

Comply

Comply

Date of release: 26 June 2019

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C.E.O.

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