

QUALITY ASSURANCE CERTIFICATE



PureSperm® 40/80

For preparation of density gradients used to separate human sperm.

Containing: 2 x 20 mL

Catalogue no: PSK-020

Batch:

020PS40XH25

020PS80XH28

Production date:

25 August, 2017

28 August, 2017

Expiry date:

24 August, 2019

27 August, 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

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

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C.E.O.

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