PRODUCT DATA SHEET

ELAREM™ Ultimate-FDi

ELAREM™ Ultimate-FDi

GMP Grade

+ **VIRUS-INACTIVATED FOR HIGHEST SAFETY**

+ **HIGHLY EFFICIENT CELL PERFORMANCE**

+ **NO HEPARIN ADDITION REQUIRED**

+ **SUITED TO CELLULAR THERAPEUTICS**

ELAREM™ Ultimate-FDi is a virus-inactivated and fibrinogen-depleted Human Platelet Lysate of US origin. The cell culture supplement is tested and released in confirmity with the relevant cGMP guidelines.

The final product is virus-inactivated in order to comply with the guidelines for clinical applications. Virus panel testing is per- formed according to ICH and EMA guidelines (ICH Q5A (R1) and CPMP/BWP/268/95). The virus-inactivation procedure has no negative impact on growth factor and cytokine concentration.

Due to the combination of highest safety standards and efficient cell perfomance, ELAREM™ Ultimate-FDi is suited to clinical trial and therapeutic cell manufacturing needs.

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PRODUCT	APPLICATION	SIZE	HEPARIN REQUIRED	STORAGE	SHELF LIFE*	ORDER NUMBER
ELAREM™ Ultimate-FDi	GMP Grade	50 mL	No	-20°C	2 years	UL40622
ELAREM™ Ultimate-FDi	GMP Grade	100 mL	No	-20°C	2 years	UL40822
ELAREM™ Ultimate-FDi	GMP Grade	500 mL	No	-20°C	2 years	UL41022

* Shelf-life duration is determined from date of manufacture, continuously stored frozen in original bottle.

BACKGROUND

Cell expansion in animal-free conditions remains a major challenge in cell culture. With our ELAREM™ Platform Technology, we developed animal component-free solutions that cover all applications, from academic research to pre-clinical research and cell therapy – one solution at a time.

As one part of our Human Platelet Lysate Platform, ELAREM™ Ultimate-FDi is suited to the requirements of evolving global regulations regarding the reduction of adventitious agent transmission (according to the Euro- pean Pharmacopeia General Chapter 5.2.12).

Despite high testing standards, safety guidelines require virus inactivation treatments of blood products for therapeutic and clinical use. The gamma-irradiation of the final product qualifies ELAREM™ Ultimate-FDi for cellular therapies.

Since fibrinogens are depleted during manufacture, coagulation of the complete medium is inhibited. This eliminates the need to add an anticoagulant with ELAREM™ Ultimate-FDi. Traces of a xeno-free anticoagulant may be present in the Human Platelet Lysate.

INTENDED USE

ELAREM™ Ultimate-FDi is for *in vitro* and manufac-turing use only. The product is not intended for direct therapeutic use. For safety precautions, please see appropriate Safety Data Sheet (SDS).

STORAGE AND STABILITY

ELAREM™ Ultimate-FDi products are stable un-til the expiry date stated on the label. ELAREM™ Ultimate-FDi is most stable when stored frozen at -20°C to -40°C until use.

PARTICULATE FORMATION

Insoluble particles may form in thawed ELAREM™ Ultimate-FDi. Particulate formation does not affect cell culture performance. If removal of insoluble particles is desired, please follow our Technical Data Sheet.

STERILITY

ELAREM™ Ultimate-FDi is aseptically processed. Microbial cultures tested negative. Quality control testing is carried out in a certified test laboratory.

TRACEABILITY AND PRECAUTIONS

ELAREM™ Ultimate-FDi is manufactured from platelet units obtained from healthy donors at licensed blood centers. Blood donors have been qualified according to current FDA guidelines for donor eligibility criteria.

PRODUCT SUPPORT

If you have any product-related questions, please feel free to contact us by e-mail at contact@cellmedex.com.

ORDER DIRECTLY ONLINE:

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