

# Batch Release Certificate

**Product name:** PentaHibe® Base  
Cryoprotective Agent, 40% pentaisomaltose solution

**Specification No.:** 90003

**Batch No.:** xxxxx

**Volume:** 40 mL

**Manufacturing date:** mmmm\_yyyy

**Expiry date: (2 years):** mmmm\_yyyy

**Manufacturer:** Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark

Method:	Parameter:	Results of analysis:	Limits:
PIMF001	Pentaisomaltose, g/100 mL:	x	38 – 42
PIMF003	pH:	x.x	3.2 – 7.0
PIMF004	Average molecular mass, Mw:	x	900 – 1,100
PIMF004	Fractions <3 glucose units , % w/w:	x	≤12
PIMF004	Fractions >9 glucose units , % w/w:	x	≤18
PIMF005	Bacterial endotoxins, IU/ml:	x	<5
PIMF006	Sterility:	Complies	Complies
PIMF007	Sub-visible particles:	Complies	Complies
PIMF008	Visible particles:	Complies	Clear solution, practically free of visible particles.
PIMF009	Absorbance (375 nm, x % sol., 1 cm):	x.xx	≤0.50

I hereby certify that the above information is authentic and accurate. This excipient batch has been manufactured, including quality control in full compliance with the above mentioned specifications.

Date (dd.mm.yyyy):

Heidi Skjødt Andersen, Senior Quality Director