

Batch Release Certificate

Product name: PentaHibe® Complete
Cryoprotection medium with pentaosmaltose and 2% DMSO

Specification No.: 90005

Batch No.: xxxxx

Volume: 50 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:
EP	Pentaisomaltose, g/100 mL:	x	8 – 12
EP	Albumin, g/100 mL:	x.x	3.0 – 5.0
Bradford	DMSO, g/100 mL:	x.x	1.6 – 2.4
EP/USP	pH:	x.x	6.8 – 7.8
EP/USP	Bacterial endotoxins, IU/ml:	x.x	≤0.50
EP/USP	Sterility:	Complies	Complies
EP/USP	Sub-visible particles:	Complies	NMT 600 particles ≥25µm NMT 6000 particles ≥10µm
Visual	Visible particles:	Complies	Clear solution, practically free of visible particles.

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