

 **DYNTEC**

Address	DYNTEC spol. s r. o. Pražská 328 411 55 Terežín, Czech Republic	Telephone	+420 416 782 251
		Fax	+420 416 782 575
		E-mail	dyntec@dyntec.cz

Manufacturer's protocol for submission of an IVMP
to a Competent Authority of Hungary
for OBPR/OCABR

CANGLOB P

Batch No. 131018

DYNTEC spol. s r. o. November 2018

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2 SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name: CANGLOB P

International non-proprietary name (INN) /Ph Eur name/ common name of product (whichever is appropriate): CANGLOB P

Batch number(s) of: Finished product (final batch): 131018

Final bulk: 131018

Pharmaceutical form of finished product: Suspension for injection

Type of final container: Glass vial

Date of start of period of validity (start of titration/potency test): 24th October 2018

Storage temperature: 2 - 8 °C

Name and address of manufacturer: DYNTEC spol. s r. o.
Pražská 328, 411 55 Terezín, Czech Republic

Name and address of the batch release site (if different from that of manufacturer): -

For accuracy	
Quality assurance	
Date	Signature
<u>20.11.18</u>	<u>[Signature]</u>



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3 PRODUCTION INFORMATION

Site of manufacture for each antigen (whenever more than one DYNTEC spol. s r. o. production site exists):
Pražská 328, 411 55 Terezín, Czech Republic

3.1 STARTING MATERIALS

3.1.1. Virus seed lots

Master seed material:	<u>CPV</u>	MS-batch number:	<u>CPV BR 1D 4-98</u>
Date of last testing:	<u>2005</u>		
Working seed material:	<u>CPV</u>	WS-batch number:	<u>CPV BR 2D 3-99</u>
Date of last testing:	<u>2005</u>		

3.1.2. Substrates (as appropriate; one or more of the following subparagraphs should be used)

3.1.2.1 Eggs for production

Supplier:	<u>AV UMG ČR, Koleč, Czech Republic</u>
Flock No.:	<u>871b</u>
Date and result of SPF-testing:	<u>No.</u>

3.1.2.2 Primary avian cells

Date and result of SPF-testing of source material:	<u>No.</u>
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3.1.2.3 Permanent cell line

Master cell seed:	<u>CRFK</u>	MCS-batch number:	<u>CRFK 1D 20-96</u>
Date of last testing:	<u>2005</u>		
Working cell seed:	<u>CRFK</u>	WCS-batch number:	<u>CRFK 2D 4-97</u>
Date of last testing:	<u>2005</u>		

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5 CERTIFICATION BY THE MANUFACTURER

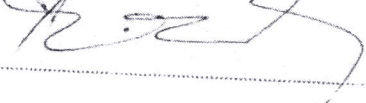
Certification by qualified person taking the overall responsibility for production and control of the product:

I herewith certify that CANGLOB P batch No. 131018 was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirement and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended by Directive 2004/28/EC.

Name: Ladislav Pažout, D.V.M. et M.Sc.

Function: Qualified person

Date: 20. 11. 2018

Signature: 

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