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QCZD229QCX3061

ANALYSIS CERTIFICATE

Product	CANVAC R suspension for injection
Batch No.	130819
Volume	13 000 packs 5 x 10 doses Romania 200 packs 60 x 1 dose Romania
Manufacture Date	2019-08-20
Expiry Date	07/2021

Appearance: White or pink liquid containing readily dispersible sediment.

Packing size: 1 ml and 10 ml of product in the glass vial.

Tests		
Analysis	Specification	Results
Utilizable Volume	Utilizable volume must be higher than nominal volume	Passed
pH Volume	7.20 to 8.20	7.50
Volume of thiomersal	NMT 0.010 %	0.008 %
Algeldratum Volume	1.40 – 6.50 mg.ml ⁻¹	4.91 mg.ml ⁻¹
Airtightness	The vials must be airtight closed	Passed
Sterility	The product must be sterile	Passed
Residual live virus	Residual live virus must not be proved	Passed
Identity	Identity must be proved	Passed
Efficacy - serology	Potency of testing batch > 2 IU/ml, (p <= 0,05)	Passed > 2 IU/ml p = 0,007

Date of Issue	2019-09-19	Valid till	07/2021
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