


CERTIFICATE OF ANALYSIS

product	NEOCORT, eye- and eardrops	date of manufacture	06.2016
code	15070	batch number	1608249.01
		date of expiry	06.2017

specifications	results	requirements
Appearance	conform	resuspendable white homogeneous suspension
Particle size	conform	100% ≤ 25 µm
pH value	6.1	5.0 – 7.0
Density	1.00	0.997 - 1.017 g/ml
Active ingredients:		
- Identification		
Prednisolon acetate	positive	positive identification
Neomycin sulphate	positive	positive identification
- Quantitative analysis		
Prednisolon acetate	5.04	4.75 – 5.25 mg/ml
Neomycin sulphate*)	2.98	2.85 – 3.15 mg/ml
Preservatives	conform	within limits
Sterility	sterile	sterile
Container	conform	dropper bottle, 5 ml

*)Component not tested. Result declared on the basis of the production amounts.

remarks
 We hereby certify that the above mentioned information is authentic and accurate. This batch of product has been manufactured, including packaging / labeling and quality control in full compliance with the GMP-requirements of the local regulatory authority and with the specifications as agreed with the marketing authorization holder/contract giver of the importing country. The batch processing, packaging and analyses records were reviewed and found to be in compliance with GMP.

date of report	Quality Control Department
27-9-2016	 P.O. Box 78 3440 AB Woerden Holland Ir. A.P.F. Philipsen Qualified Person