E Control tests on the finished product

Introduction

The table below presents an overview of the tests performed on the finished product. More details on the test procedures are given on the following pages.

Parameter tested	Test procedure	Limits of acceptance
General characteristics of the finished product		
Appearance	SOP 94203-E	Cream coloured homogeneous oil emulsion.
Centrifugation	SOP 94201-E	At the time of production, the water phase of the emulsion should not exceed 1% of the total emulsion volume after centrifugation.
Viscosity	AM 94225	At the time of production: 140-250 mPas (at 20°C, shear rate 225 1/s) During shelf life: 120-250 mPas (at 0°C, shear rate 225 1/s)
Free formaldehyde [1)]	Ph. Eur./ SOP 94039-E	≤ 0.4 g/l
Identification[2)] and assay of the active substances		
Potency	SOP 94275-E	
- *L. anguillarum* O1		Relative Percentage Survival (RPS) is calculated at 60% mortality in control group. RPS_{60} ≥ 75%
- *P. damselae* subsp. *piscicida*		Relative Percentage Survival (RPS) is calculated at end of mortality in control group (no fish have died over a period of 2 days). RPS_{end} ≥ 60%
Sterility and purity test [3)]		
Sterility	Ph. Eur./ AM 94001	No contamination

1) The content of free formaldehyde in the final product is calculated based on results from analysis performed on the inactivated virus suspension before emulsification to final bulk vaccine.
2) The identity of the active substances is demonstrated by the batch potency test
3) The sterility test is the only test performed on the final product to show freedom from contaminating agents. The production and control of the starting materials and the in-process controls will ensure freedom from extraneous agents