

Overview

- Concept of Vaccine Testing
- Scoring System
- Classical Swine Fever

Concept of Vaccine Testing

- Purity
- Safety
 - tests in animals
- Potency
 - tests in animals

Safety Tests

- Injection of
 - single dose
 - overdose
 - repeated dose
- into target species
- ✓ *usually no major animal suffering*

Potency Tests

- Vaccination of target animals
 - After onset of immunity: Infection of vaccinated and control animals
- ! *Major animal suffering involved*

Parameters for Evaluation of Potency Tests

- Observation period
 - usually equal for vaccinated and control animals
- Clinical signs or death
 - different for vaccinated and control animals

Control Animals

- Validity of the test
 - High percentage of controls must show clinical signs or death after vaccination
- Signs needed to demonstrate the validity of the test ?

Vaccinated Animals

- Demonstration of the protective activity of the vaccine
 - Low percentage of affected animals
- Signs considered as lack of protection

Scoring System

- Definition of a healthy animal
- Sound knowledge of the
 - Disease
 - Clinical signs after experimental infection
 - Infectious agent
- Definition of specific parameters
 - Clinical parameters
 - Microbiological parameters

Classical Swine Fever (CSF)

- Highly contagious viral disease for pigs
- “Hemorrhagic fever”
- Different virus strains show different pathogenicity
- Acute or chronic forms
- Vaccines available since 1925

Classical Swine Fever (CSF)

Ph. Eur. (proposed text, *PHARMEUROPA* 17.4)

- “ The use of humane endpoints can allow to avoid unnecessary suffering of animals after the virulent challenge.”
- “ The test is invalid if fewer than 50 per cent of the control piglets die and if fewer than 100 per cent of the control piglets show clinical signs of disease within 21 days of challenge.”
- “ The vaccine complies with the test if the minimum dose stated on the label corresponds to not less than 100 PD₅₀.”

Scores Applied with CSF

- 0 Normal condition
- 1 Slight deviation of normal status
- 2 Clear signs of disease
(recovery possible)
- 3 Severe signs of disease
(recovery questionable / unlikely)

Scores Applied in CSF infections

Parameter		score 0	1	2	3
1	Liveliness	attentive	reduced	tired	dormant
2	Body shape	full stomach	empty stomach	thinned muscles	emaciated
3	Walking	coordinated	hesitant	ataxia	severe lameness
4	Skin	light pink	reddish	purple	black-reddish
5	Appetite	greedy	slow eating	no eating	no interest in food
6	Defecation	soft	dry	diarrhoea	bloody diarrhoea
7	Body temperature (# days >40°C)	3	4	5	6

Humane Endpoints

evaluation of individual animals

Daily score: sum of scores of each parameter

- Daily score >12
 - euthanasia
- Score 3 in parameter 3, 4, 5 or 7
 - euthanasia

Humane Endpoints

Veterinary Vaccine Testing

→ Knowledge of

- pathogenesis
- clinical outcome of experimental infection

→ Scoring system

→ Criteria for euthanasia