

LOCAL TOLERANCE OF INTRAMAMMARY PREPARATIONS IN COWS

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LOCAL TOLERANCE OF INTRAMAMMARY PREPARATIONS IN COWS

1. OBJECTIVE

The objective of this note for guidance is to provide guidance for the determination of local tolerance of intramammary preparations intended for use in both lactating and non-lactating cows.

2. METHOD

Comparative trial before and after treatment in which the animals are their own controls. Untreated animals should also be included in the study. Non-lactating (dry) cow preparations should be tested in lactating cows. The evaluation criterion is the cell count in the treated udder quarters in combination with clinical criteria (appearance of the udder and of the milk) and zootechnical criteria (milk yield). The study unit may be the cow or the quarter, according to the trial design.

3. DEFINITION OF ELIGIBLE SUBJECTS

The criteria for inclusion are the following:

- cows in lactation, each udder quarter of which presents a geometric mean cell count on the last 6 milkings before treatment of less than 200 000 cells/ml;
- cows which have not been given any anti-infectious and/or anti-inflammatory treatment within the 30 days preceding the trial;
- cows free of any intercurrent diseases;
- cows which are bacteriologically negative in pre-treatment milk samples;
- cows free of teat lesions.

4. TREATMENTS

4.1 Studied treatments

The product must be administered into each of the four udder quarters under the normal conditions of use stated in the application for marketing authorisation with regard to dosage and frequency of administration.

4.2 Associated treatments

Associated treatments are not permitted.

5. PRACTICAL EXECUTION OF THE TRIAL

5.1 Subjects and numbers required

Trial subjects should be cows in lactation, including cows in first lactation, and cows with a milk yield in excess of 10 l/day and a stable somatic cell count.

The numbers of animals and the timing of treatment should be justified.

5.2 Sampling procedure

At each one of the following times, each quarter must be milked out and the milk from each quarter assayed:

- at various times pre-treatment (day -3 to day 0);
- at each milking during treatment;
- at each milking following treatment for a minimum of 6 milkings up to return of somatic cell counts to pre-treatment basal levels.

5.3 Clinical examination

A clinical examination by the local investigator must be carried out at each milking, the following points being noted:

- any alteration in the appearance of the udder;
- any alteration in the appearance of the milk;
- any behavioural or clinical abnormality in the cow.

5.4 Other measures

The total milk yield of each cow should be recorded at each milking at the times stated in item 5.2 above.

5.5 Analysis of milk samples

The milk samples from each udder quarter should be subjected to cell counts by the techniques recommended by the International Dairy Federation (IDF).

6. EXPRESSION OF RESULTS

All cows included in the trial must be described in the final report. The report and description of any abnormality of clinical behaviour of the cow or of the udder and/or of the appearance of the milk must be reported and commented upon. The milk yield of each cow and the cell counts of each udder quarter must be recorded in a summary table.

7. ANALYSIS

7.1 Evaluation of results

The evaluation should be based on the following:

- absence of significant alteration in the macroscopic appearance of the udder;
- absence of significant alteration in the appearance of the milk;

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- the time taken for the return of somatic cell counts in treated quarters to pre-treatment basal level is equal to or less than the withdrawal period proposed for the product in respect of products for lactating cows);
 - absence of pain or systemic clinical side effects following infusion of products.

7.2 Statistical analysis

For the milk yield: The mean daily milk yield of each cow before treatment is compared with that after completion of the treatment by means of appropriate statistical tests. The same procedure is used for all the animals.

For the cell counts: A comparison is made for each cow between the geometric mean cell counts prior to treatment and the mean cell count after completion of the treatment by means of appropriate statistical tests. The same procedure is used for all the animals.