I. INTRODUCTION

Nobilis Diluent Oculo Nasal is an inactive solution for reconstituting freeze-dried Nobilis vaccines which are approved for administration to poultry via the eyes or nose. It contains no antigens or other active ingredients, but consists mostly of sterile buffered* saline and disodium ethylene diamine tetraacetic acid (disodium edetate). There are no warnings or special precautions for using the diluent itself, although these may be specified for the particular vaccine with which the diluent is used. The product is presented in 35 or 84 ml polyethylene terephthalate (PET) vials.

The freeze-dried vaccines are reconstituted by aseptically transferring around 5 ml of the diluent into the vial of freeze-dried vaccine, mixing thoroughly, and then transferring back into the diluent vial and mixing again. This is done immediately prior to use.

II. QUALITY ASPECTS

Product Development and Composition

There are no active substances. The product contains the following ingredients:

Ingredient	Function
Sodium chloride	To make the solution isotonic
Potassium dihydrogen phosphate	To ensure the correct pH (degree of acidity) is maintained
Disodium phosphate dihydrate	
Disodium edetate	To prevent precipitation
Patent Blue V (E131)	To distinguish vaccinated from unvaccinated birds
Water for injections	To provide the liquid component of the diluent

The diluent is intended for oculo/nasal administration of certain live poultry vaccines in the Nobilis range. It is marketed with one of a range of vaccine pellets, with the freeze-dried pellet containing the active ingredient(s). Phosphate salts provide buffering for the isotonic solution of sodium chloride, disodium edetate prevents precipitation and the Patent Blue dye facilitates checks on vaccine application.

Active Substance

There are no active substances in this product.

Other Ingredients

Certificates of analysis have been presented for all the ingredients and these are all listed in a pharmacopoeia. There are no materials of biological origin in the product and there is therefore no risk of transmitting animal spongiform encephalopathy agents (TSEs) by using it.

Packaging materials

The finished product is presented in 35 ml (containing 31.5 ml of product) and 84 ml (containing 79 ml) PET (polyethylene terephthalate) vials. The containers and stoppers are sterile, and made of standard materials.

* "buffered" means that substances are added to prevent changes in pH (degree of acidity).

Manufacture of the Product

All production steps are performed according to GMP*. Where applicable, conditions, equipment and materials are sterile. The product is produced in 50 – 500 litre batch sizes. A detailed description of the manufacturing process has been provided by the company and appropriate checks are carried out during production. The product is sterilised by filtration and filter integrity is assessed prior to and after filtration. Final production steps are filling and capping, followed by quality control.

Data have been provided to show that the diluent does not have adverse effects on the vaccines for which it is designed.

Finished Product Quality Control

Standard appropriate tests (visual tests, pH, identity) are used to check the quality of the finished product. Its sterility and the volume in the vials are also checked. Because the finished product is marketed with one of a range of vaccine pellets, a batch test is carried out to show freedom from virucidal effects that could affect the efficacy of the vaccines.

Results of the analysis of 3 consecutive batches of finished product have been provided, and comply with the required specifications.

Stability of the product

Finished Product

Stability data for 9 batches of the finished product were provided. Based on this information, a shelf life of 48 months was accepted.

In-Use

The in-use shelf life is that specified for the vaccine for which Nobilis Diluent Oculo Nasal is used as the diluent.

CONCLUSIONS ON QUALITY

The part of the dossier relating to the quality of the product presented satisfactory descriptions of the production and quality control procedures, including appropriate diagrams. The method of manufacture was well described, and the in-process controls detailed in full. Risk of transmission of TSEs was shown to be non-existent as there were no starting materials of biological origin.

The finished product tests, including the lack of virucidal activity test, ensure a safe and consistent product. Based on the stability data provided, the current shelf life is justified.

* GMP = Good Manufacturing Practice

III. SAFETY ASPECTS

Nobilis Diluent Oculo Nasal is intended for use with Nobilis poultry vaccines. This diluent has been tested for safety in conjunction with the specific poultry vaccines for which it is produced. Given the nature of the diluent, and the intended use there is no requirement for any other specific safety data. There are no concerns from the use of this diluent for user, consumer, environmental or animal safety.

IV. CLINICAL ASPECTS

Nobilis Diluent Oculo Nasal is intended for use with Nobilis poultry vaccines. The specific poultry vaccines for which it is produced have been tested for efficacy when resuspended in Nobilis Diluent Oculo Nasal. Given the nature of the diluent, and the intended use there is no requirement for any other specific efficacy data.

V. OVERALL CONCLUSION ON THE PRODUCT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for man and the environment is acceptable.

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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