

Transgene's proposal to participate in Assignment of Particle concentration. RFP 8.0

Determination of Adenovirus Particle Concentration *via* Spectrophotometric Analysis

1 . Personnel qualifications, experience and training

1.1 Personnel involved in performing the procedure

Catherine FAHRNER, senior technician in Quality Control Development and Quality Control

General academic qualification:

BTS (Brevet de technicien supérieur) in Biophysics. BTS is the equivalent to the high school baccalauréat + 2 additional years of study.

Experience and training :

Employed by Transgene since 1987, 7 years in Biochemistry Department and 7 years in Development of Controls and Quality Control.

Accredited to performed the determination of adenovirus particle concentration *via* spectrophotometric analysis.

1.2 Personnel involved in reviewing the data

Edwige BONFILS, senior scientist, Head of the Quality Control Development Department

General academic qualification :

Maîtrise in Biochemistry (roughly equivalent to a B.Sc.). D.E.A in Organic Chemistry (roughly equivalent to a M.Sc.). PhD; in Biochemistry, subject : Targeting of antisense oligonucleotides *via* glycosylated carriers.

Experience and training :

Seven year experience in research, development and production (oligonucleotide chemistry, biochemistry and molecular biology) with Appligene. Employed by Transgene since September 1998.

Accredited to review the data of the quantification of adenovirus preparations *via* spectroscopic analysis.

2. Equipment

2.1 UV-VIS spectrophotometer

Uvikon XS (Bio-Teck Instrument)

IQ, OQ, PQ performed at reception of the equipment.

Annual qualification according to the European Pharmacopoeia

2.2 Balance:

AT261 Delta range (Mettler)

Annual calibration and qualification by an trained and qualified technician of Mettler company.

2.3 pH meter: Delta 345 (Mettler)

Calibration with standard solutions before each measurement set

3. Delay to perform the procedure, and review and report results

Two weeks after sample receipt

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Determination of adenovirus particle concentration via anion exchange HPLC

1. Amount of Ad5 WT Reference Material required

2.0 x 10¹¹ particles

2. Personnel qualifications, experience and training

2.1 Personnel involved in performing the procedure

Catherine FAHRNER, senior technician in Quality Control Development and Quality Control

General academic qualification:

BTS (Brevet de technicien supérieur) in Biophysics. BTS is the equivalent to the high school baccalauréat + 2 additional years of study.

Experience and training :

Employed by Transgene since 1987, 7 years in Biochemistry Department and 7 years in Development of Controls and Quality Control.

Accredited to performed the determination of adenovirus particle concentration *via* anion exchange HPLC.

2.2 Personnel involved reviewing the data

Edwige BONFILS, senior scientist, Head of the Quality Control Development Department

General academic qualification :

Maîtrise in Biochemistry (roughly equivalent to a B.Sc.). D.E.A in Organic Chemistry (roughly equivalent to a M.Sc.). PhD; in Biochemistry, subject : Targeting of antisense oligonucleotides *via* glycosylated carriers.

Experience and training :

Seven year experience in research, development and production (oligonucleotide chemistry, biochemistry and molecular biology) with Appligene. Employed by Transgene since September 1998.

Accredited to review the data of the quantification of adenovirus preparations by anion exchange HPLC.

3. Equipment

3.1 HPLC

600S chromatography system equipped with a 717 autosampler and a 996 photodiode array detector (PDA) piloted by Millenium 32 software (Waters).

Initial IQ, OQ, PQ performed at reception of the equipment

Operating re-qualification each 18 months perform by a trained and qualified technician of Waters company following Waters recommended procedures.

3.2 Balance

AT261 Delta range (Mettler)

Annual calibration and operating qualification perform by a trained and qualified technician of Mettler company

3.3 pH meter

Delta 345 (Mettler)

Calibration with standard solutions before each measurement set

4. Delay to perform the procedure, and review and report results

Two weeks after sample receipt.

5. Procedure

See specific document : Standard operating procedure for the determination of Adenovirus particle concentration by HPLC.