NEW APPLICATIONS FOR ACCELERATORS IN PHARMACEUTICAL PROCESSES

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Didier MORISSEAU
GETINGE LINAC TECHNOLOGIES – ORSAY, FRANCE

www.linactechnologies.com
SUMMARY

- GETINGE LINAC TECHNOLOGIES SAS
- SterStar™ LOW ENERGY SYSTEM
- SterBox™ MEDIUM ENERGY SYSTEM
- BENEFITS FOR THE END-USER
- PRACTICAL ASPECTS OF INTEGRATION IN THE PHARMACEUTICAL PROCESS
GETINGE LINAC TECHNOLOGIES SAS

- GETINGE LINAC is situated in Orsay, 20 km south of PARIS, FRANCE:
  - Surface area: 1 150 m²
  - 27 employees
  - Sales (2008): 8 500 K€

- Member of the GETINGE group
  - 12000 employees worldwide
  - Sales (2008): 1852 M€
SterStar™ low energy system
STANDALONE IN-LINE SURFACE STERILIZATION TUNNEL
SterStar™ E-BEAM TUNNEL
STERILE TRANSFER

E-beam sterilization tunnel

Tub of pre-sterilized RTF syringes

Aseptic filling line
SterStar™ E-BEAM TUNNEL
FOR SURFACE DECONTAMINATION

- TO STERILIZE TUB SURFACE
- INCLUDING HIDDEN AREAS
  (25 kGy under the first Tyvek® guaranteed)
- WITHOUT
  - Glass coloration
  - Ozone accumulation
  - Tub (ink) deterioration
3 low energy e-beam accelerators are installed at 120° to sterilize the entire surface of the TUB.

Continuous throughput:
- 6 tubs per minute, i.e. 36,000 syringes per hour (100 syr. tubs)
- 57,600 syringes per hour (160 syr. Tubs)
KEVAC LOW ENERGY ACCELERATOR

Energy : variable between 10 and 200 KV
Power : 800 W
Average beam current : from 0 to 5 mA
Scanning width : from 7 cm to 20 cm (according to tub size)
Conveyor speed : according to the throughput
HV generator : continuous voltage
SterStar™ E-BEAM TUNNEL
NEW DESIGN

- Outer stainless steel cladding
- Aseptic tunnel
- Static shield
- In-line conveyor
- Shielding
- Recirculated air flow (iso 5 class)
- Aseptic tunnel
- 3 accelerators for e-beam treatment
27 e-beam units of this type are installed or under construction throughout the world. 19 of these have been supplied by Getinge Linac.
SterBox™
medium energy system
STANDALONE IN-LINE
TERMINAL STERILIZATION TUNNEL
Terminal sterilization of filled or empty syringes and vials, inline with high speed filling machine.

Terminal sterilization of medical devices
STERBOX Design Scope

Accelerator
Compact and powerful

Infeed Transfer

Throughput:
300 units per min

Shielding
High energy shield with fast, easy access

Conveyor
Transport belt:
Ozone and X-ray resistant
MEVAC accelerator inside shield

Energy : 5 MeV
Power : 5 kW
Average Beam Current : 1 mA
Scanning Width : Bidirectional scan XY
Scanning Area : Up to 10 cm x 10 cm
Conveyor Speed : Up to 10 m / min
HV Generator : Solid State Modulator
STERBOX in the workshop

SterBox Video
2 Units are installed for a US customer
BenEFits of e-bEAM for the pharmaCeutical manufacturer

- In-line in-house machines for surface or core sterilization:
  - Logistics & Capital Assets Economy
- Continuous treatment with recording of the GMP parameters:
  - Quality & Safety
- Flexibility of tuning for better dose distribution:
  - Quality & Economy
- Reliability and easy maintenance on site:
  - Quality & Economy
- Stand alone equipment: easy to install - can be moved.
  - Economy
- Low operating costs.
  - Economy
- Packaging sterilization just prior to filling:
  - Quality & Economy
PRACTICAL ASPECTS OF INTEGRATION IN THE PHARMACEUTICAL PROCESS

- **VALIDATION**
  - System is completely validated
  - Simple to validate
  - Traceable
  - Recordable
  - Meets standards

- **DOSIMETRY / STERILIZATION**
  - Complete sterilization: 7 log decrease
  - Regular dosimetry checks

- **THROUGHPUT AND ROBUSTNESS**
  - Fast continuous sterilization

- **ENVIRONMENTAL IMPACT**
  - « Green » technology
  - No chemicals used
  - Minimal exhaust products
  - Comparatively low energy consumption

- **INTERFACING WITH PROCESSES**
  - Fully integrated in the production process both upstream and downstream

- **PHARMA GMP DOCUMENTATION**
  - FS / SDS / HDS / IQ / OQ / PQ... electronic signatures and printed paper files
We make life safer for you

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