



NIPRO
PHARMAPACKAGING

QUALITY LEVELS

The process of defining the right quality level for primary packaging is a complex, involved process. In order to ensure the optimal match, there must be understanding and collaboration: specific data must be exchanged, requirements discussed, and numerous parameters defined.

Our Nipro Quality Levels form the perfect base to fine-tune your quality and service requirements, thereby providing you with the optimal packaging solution.

eNgage...

in'geɪdʒ :
Participate / Become involved in

eNgage with Nipro to develop a tailored packaging quality, whereby we apply our profound analytical competencies and align our cutting-edge production and inspection technologies to satisfy your unmet drug product requirements.

eNhance..

in'hæns :
Increase / Further improve

eNhance the pre-fillable syringe quality to meet the requirements of highly sensitive drugs, administered through manual injection or auto injectors.

eNable.

i'neɪbl :
Activate / Make something operational

eNable a packaging quality that answers to the prevailing drug product requirements.

PRE-FILLABLE GLASS SYRINGES FINE-TUNED TO YOUR NEEDS!



BENEFITS

Optimized total cost of ownership

- **Reduced risk of false rejections of filled syringes thanks to superior cosmetic quality**
100% camera inspection with tighter specifications on cosmetic defects
- **Minimized risk of syringe breakage during Fill-Finish operations**
laser-based glass cutting and no glass to glass contact increase packaging mechanical durability

Reliable and safer administration, manual and via injection devices

- **Optimal integration of syringes into injection devices**
tighter dimensional tolerances through advanced forming and inspection technologies
- **Minimized risk of syringe breakage during syringe assembly or device use**
laser-based glass cutting and no glass to glass contact increase packaging mechanical durability
- **Superior syringe functional performances even with viscous drugs**
highly consistent silicone oil distribution monitored 100% in-line
- **Next level of needle and container closure integrity**
100% X-ray inspection in-line

Higher compatibility between drug and packaging

- **Specified low tungsten residuals lessen risk of tungsten-induced protein aggregation**
guaranteed through ICP-MS results on CoA
- **Lessened risks of protein aggregation and particle formation**
consistent ultra low silicone oil level
- **Reduced particle level**
innovative glass cutting technology and higher level of cleanness of secondary packaging material

Supportive services

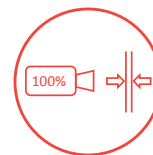
- **CoC and extended CoA**
for each batch available
- **Simple LoA request procedure**
for Drug Master Files at FDA & Health Canada



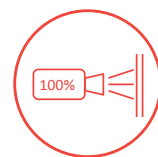
INSPECTION TECHNOLOGIES



Silicone distribution



Cosmetic inspection



Dimensional inspection

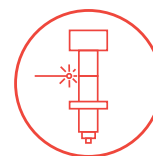


Container closure integrity

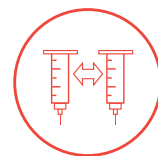
MANUFACTURING TECHNOLOGIES



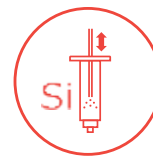
Low tungsten



Laser based cutting



No glass to glass contact



Dive in nozzle

DATA SHARING



Simple LoA request procedure



Adaptable CoC and CoA