



Specifications

Vials and bottles for oral and nasal application:

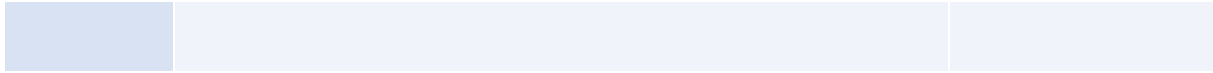
- Syrup
- Tablets
- Droppers
- Sprays / Aerosols
- U-Save
- Related products

Approval cycle

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Specifications - Vials and bottles for oral and nasal application





Acceptance of the specifications

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Yes
No

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For the company:

NAMES	FUNCTIONS	DATES	SIGNATURES

For SGD Pharma:

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NAMES	FUNCTIONS	DATES	SIGNATURES

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1. Introduction

As specified in the European Pharmacopoeia and the US Pharmacopeia, the manufacturer of a pharmaceutical product is responsible for ensuring the suitability of the chosen glass container.

According to their hydrolytic resistance, glass containers are classified as follows:

- Type I glass container: neutral glass with high hydrolytic resistance due to the chemical composition of the glass itself
- Type II glass container: usually of soda-lime-silica glass with high hydrolytic resistance resulting from suitable treatment of the surface
- Type III glass container: usually of soda-lime-silica glass with only moderate hydrolytic resistance

SGD Pharma is one of the main manufacturers of moulded glass vials and bottles for pharmaceuticals. Product Quality is a major aspect of its policy.

This can particularly be seen in:

- **The specialization of its production lines,**
- **Considerable capital outlays,**
- **Cleanliness policy (reflected in particular in its clean rooms),**
- **The training and involvement of all staff,**
- **A Quality Management System ISO 15378 certified, based on the Good Manufacturing Practice of the pharmaceutical industry,**
- **An ongoing improvement policy focused on customer satisfaction.**

Under this policy, the present Specifications for oral and nasal application vials and bottles are designed to optimize relations between the customers and supplier. Any industrial manufacturing process implies an agreement between the customer and its supplier in terms of product quality levels.

These Specifications for oral and nasal application vials and bottles define the quality level considered as acceptable by our customers and the methods used to inspect this minimum quality limit.

The aim of these Specifications for oral and nasal application vials and bottles is thus to define the acceptable quality standards by non-conformity category for the following bottles:

Vials and bottles for oral and nasal application:

- **Syrups**
- **Tablets**
- **Droppers**
- **Sprays / Aerosols**
- **U-Save**
- **Related products**

Additionally, to these Specifications for parenteral application vials and bottles SGD Pharma has defined in a Quality Agreement the quality requirements to be followed with regard to the manufacturing, testing and quality assurance operations of the products.

2. General conditions

Above and beyond these Specifications for oral and nasal application vials and bottles, SGD Pharma undertakes to pursue its continuous efforts to improve its manufacturing process and inspection methods in line with its quality insurance approach and with the Good Manufacturing Practice of the Pharmaceutical Industry in mind.

These Specifications for oral and nasal application vials and bottles are the property of SGD Pharma. The information contained herein as well as all information regarding processes, materials and inspection methods revealed to our customers shall be treated as confidential. Our customers thereby must undertake not to disclose any of the aforementioned information to any third party whatsoever.

The SGD Pharma Specifications apply to all standard vials and bottles manufactured by SGD Pharma. They may apply, after approval from our customers, to specialty vials and bottles.

As part of its Quality Insurance approach SGD Pharma might update these Specifications from time to time to reflect the changing needs of the various market segments. Such improvements will be communicated to SGD Pharma clients as per the relevant change control procedure in place.

All inspection measures taken to ensure quality complies with these Specifications for oral and nasal application vials and bottles do not imply a transfer of responsibility from the customers to SGD Pharma.

3. General specifications

3.1. Compliance with pharmacopeias

For glass bottles, these requirements basically relate to:

- Hydrolytic resistance
- Light transmission for amber glass
- Arsenic

SGD Pharma manufactures its pharmaceutical bottles in compliance with the requirements of European and American pharmacopeias. This implies:

- Upstream from the production process, a rigorous selection of raw materials and appropriate glass compositions
- Downstream from the production process: strict inspections according to the Specifications

The non-compliance of any one of the above parameters is considered to be a class A non-conformity (see § 4).

The pharmaceutical glass vial and bottles manufactured and commercialized by SGD Pharma are in compliance with:

- Monograph 3.2.1 Glass container for pharmaceutical use of the current European Pharmacopeia
- Chapter < 660 > Container – Glass of the current US Pharmacopeia

3.2. Production environment / Clean room

In order to limit the risk of bottles contamination, the 'cold end' (downstream part of the production line where production inspection and secondary packing take place) are located in rooms with controlled atmosphere.

The particle rate in the air is regularly measured to ensure that such rooms always comply with class ISO 8 of ISO Standard 14644-1. This class corresponds to class 100 000.

3.3. Packaging waste / Heavy metals

The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in SGD Pharma glass vials and bottles is less than 100 ppm by weight (see Directive 94/62/EC on packaging waste - Article 11).

3.4. Compliance with TSE/ESB

The raw or sourced materials or reagents used in the manufacturing process are not derived from animals or humans and thus comply with EMA/410/01.

3.5. External surface treatment

Hot and cold surface treatments applied to the external surface of the vials and bottles improve its mechanical resistance, and so reduce the risk of breakage on the processing/packing line.

It also reduces the risk of scratching and facilitates vials and bottles flow on the processing/packing line (improved bottle « slide »).

Therefore, SGD Pharma generally recommends this type of treatment.

To avoid contamination of the internal surface of the vials and bottles, SGD Pharma systematically uses:

- A so-called « neck finish protection » device for hot treatment,
- A spray treatment in between rows for cold treatment.

3.6. Vials and bottles production drawing

For each product, there is an existing Technical Drawing stating the main dimensions and overflow specifications.

For speciality products, the customer must approve the drawing by writing prior to production launch.

The dimensions subject to inspection are those indicated with a tolerance on the drawing. Reference to standard (ISO, CETIE ...) are indicated on the drawing applicable to the article.

The approximate weight on the technical drawing is only indicative, only the capacity is considered as a technical specification.

3.7. Packaging palletization

SGD Pharma packs the vials and bottles inside a shrink-wrap plastic film (with a welded sealing) usually called “packs”, directly on the production line.

Other types of packaging are available on customers request.

The packing and palletization specifications are defined and summarized in packing specification sheets that can be supplied upon customers request.

Standard packaging for the product is as described:

- A wooden pallet in compliance with the standard ISPM 15 and the dimensions indicated in the packing specification sheets,
- A plastic foil is hung in between pallet and first layer
- The number of vials and bottles by unit of packs and by layers are specified in packing specifications sheets
- A divider is inserted in between layers of shrink-wrap packs
- A shrink-wrap plastic cover maintains the vials and bottles on the pallet.

3.8. Vials and bottles shelf life

The shelf life of the vials and bottles Type I, Type II and Type III is at least 6 years from the date of manufacturing date.

3.9. Vials and bottles storage

Storage time will depend upon humidity and temperature in the storage place. These are the most influential parameters in the natural process of glass exudation. Aging in the presence of moisture and temperature changes can result in the migration of alkali elements (Na_2O) present in the glass on its surface. This presence often takes the form of a whitish bloom.

At SGD Pharma the pallets of vials and bottles are stored inside a warehouse. In there, a rodent control program is in place. The temperature inside, is similar to the outside temperature, the warehouse insulation prevents big temperature variations.

The pallets are stackable on a five-meters maximum height, unless otherwise specified.

3.10. Ready for use statement

As described in this SGD Pharma Standard Specifications for oral and nasal application vials and bottles listed hereabove, SGD Pharma implemented the following in order to limit the risk of contamination: final product inspection in Clean Rooms ISO 8 (100 000), and clean room environment monitoring for particles as per ISO 14644.

Additionally, turn and blow equipment is in place at the end of all cold end lines within the clean rooms ISO 8 (100 0000), clean room environment is also monitored for microbiological contamination as per internal procedures and adequate controls are in place to detect non-conforming products.

The products manufactured under the aforementioned specifications are hence ready for use with limited risks. Nevertheless, it is not possible to offer absolute warranty of non-contamination due to product handling, loading unloading and transportation of the bottles.

As a consequence, it is the responsibility of our customers to ensure that the risk to the patient or to the consumer is fully assessed and that adequate validation was done and internal controls are in place.

3.11. Labelling – Traceability

All pallets are labelled.

The details on each label will identify:

- SGD Pharma item code (10 digits)
- Packing characteristics:
 - Number of items per pack (number of module)
 - Number of packs per layer
 - Number of layers per pallet
 - Number of items per pallet
- Batch number identifying the:
 - Manufacturing plant
 - Manufacturing year
 - Serial number within this year
- The pallet number

As a GMP practice, when using vials and bottles, it is essential to keep pallet labels as traceability data, compulsory to conduct an efficient investigation process in case of issue.

A sample pallet label is enclosed to the present Standard Specifications for oral and nasal application vials and bottles (Appendix 2).

3.12. Batch / lot definition

During production at SGD Pharma:

Each lot corresponds to vials and bottles manufactured consecutively on the same machine; it is thus a homogeneous batch. (Also called production run).

Certificates of Quality are issued on this same basis, i.e. each certificate corresponds to a single batch, (Appendix 3).

On delivery to the customer, each SGD Pharma shipment for a given item number and a given SGD Pharma batch number constitute an in-coming inspection batch.

3.13. Compliance certificate

As part of its quality assurance, SGD Pharma systematically issues Certificates of Quality attached to each delivery.

These certificates are related to a complete production batch. They certify the application of inspection procedures and the compliance of the products to the present Specifications.

The issue of such certificates in no way exempts the customer from its responsibility under common law.

Two samples of the certificates are enclosed to the present Specifications (Appendix 3).

3.14. Quality level – A.Q.L. / Choice

The level of quality is defined as follows:

- According to criticality, the non-conformities are ranked by class; each class is associated with a defined Acceptance Quality Limit (cf. NF ISO 2859-1).
- Imperfections, if their size does not exceed a certain threshold, will not be considered as a non-conformity. These thresholds are defined in Appendix 1; they are associated with what we call the « standard choice of vials and bottles for oral pharmaceutical products ».

On customer's request, SGD Pharma can apply different choices level, which will impact the selling price. (Cf. Appendix 1).

4. Statistical quality control

4.1. Statistical quality control method

Inspection is conducted by attributes, i.e. counting the non-conform vial as a non-conformity.

- As explained above: the non-conformities are ranked by class; each class is associated with a defined Acceptance Quality Limit.

The inspection is carried out in compliance with the sampling schedules of ISO standard 2859-1.

- The ISO standard 2859-1 tables used are the following:

- Table 1 with inspection level II or S3 to determine the sample code letter
- Table 2A (simple sampling plan – normal inspection) to determine the acceptance threshold as a function of the sample letter code and the A.Q.L.

- Inspection batch: see § 3.11

The bottles are sampled randomly from a number of pallets/packs equal to the square root of the total number of pallets/packs in the batch to be inspected.

The following table summarizes the sampling and decision rules for Level II normal inspection.

Batch size	Sampling		A.Q.L 0,40		A.Q.L 0,65		A.Q.L 1,5		A.Q.L 4	
	N		A	R	A	R	A	R	A	R
3 201 / 10 000	L	200	2	3	3	4	7	8	14	15
10 001 /35 000	M	315	3	4	5	6	10	11	21	22
35 001 / 150 000	N	500	5	6	7	8	14	15	<u>27</u>	<u>28</u>
150 001 / 500 000	P	800	7	8	10	11	21	22	<u>41</u>	<u>42</u>
> 500 000	Q	1250	10	11	14	15	<u>26</u>	<u>27</u>	<u>61</u>	<u>62</u>

NB: The figures in *underlined italics* do not appear in the tables in ISO Standard 2859 -1; but they have been calculated using the same method.

Sheet of sampling S3

Batch size	AQL	AQL	AQL	AQL	AQL	AQL	AQL	AQL	AQL	AQL	AQL	AQL	AQL	AQL
	0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0
501 - 3 200										Prel. 20 A : 0 R : 1	Prel. 13	Prel. 8	Prel. 20 A : 1 R : 2	Prel. 13
3 201 - 35 000	Prel. 1250 A : 0 R : 1	Prel. 800 A : 0 R : 1	Prel. 500 A : 0 R : 1	Prel. 315 A : 0 R : 1	Prel. 200 A : 0 R : 1	Prel. 125 A : 0 R : 1	Prel. 80 A : 0 R : 1	Prel. 50 A : 0 R : 1	Prel. 32 A : 0 R : 1		Prel. 20 A : 0 R : 1	Prel. 32 A : 1 R : 2		Prel. 20 A : 1 R : 2
35 001 - 500 000											Prel. 50 A : 1 R : 2	Prel. 32 A : 2 R : 3	Prel. 32 A : 2 R : 3	Prel. 32 A : 3 R : 4
> 500 000											Prel. 80 A : 1 R : 2	Prel. 50 A : 2 R : 3	Prel. 50 A : 3 R : 4	Prel. 50 A : 5 R : 6

4.2. Method for counting non-conformities

The number of non-conform vials per class is calculated according to the following rules:

- In case a vial presenting several non-conformities, it is only counted once; if the non-conformities belong to different classes, it is the lowest A.Q.L. that counts.
- For finished bottles, the glass and finishing non-conformities in the same class are considered cumulatively.

4.3. Definition of non-conformity classes and corresponding A.Q.L.

The non-conformity classes are the following:

- Class A non-conformities or A critical non-conformities.
- Class B non-conformities or B critical non-conformities.
- Class C non-conformities or C major non-conformities.
- Class D non-conformities or D major non-conformities.
- Class E non-conformities or E aspect non-conformities.

*** Class A non-conformities or A critical non-conformities A = 0 R = 1**

These bottles represent a risk for users.

If a non-conformity of this class is found during the delivery inspection, the inspected batch is rejected.

The A.Q.L. corresponding to A=0 R=1 varies as a function of the sample, which depends on the size of the batch to be inspected. The A.Q.L. are summarized in the following table:

Table giving the A.Q.L. for A = 0 R = 1	
Sample size	A.Q.L.
125	0,10
200	0,065
315	0,040
500	0,025
800	0,015
1250	0,010

Note:

Despite many measures aiming at ensuring a very high-quality level to its products, SGD Pharma is unable to guarantee absolute zero non-conformities.

Consequently, the A=0, R=1 rule should be used only for statistical quality control.

The discovery of a bottle with a class A non-conformity on the production line, does not automatically result in the rejection of the batch (the rejection would only be justified if, in the absence of a statistical quality control at delivery, an inspection is carried out later and reveals the presence of a significant number of bottles with this class non-conformities).

*** Class B non-conformities or B critical non-conformities**

These non-conformities are liable to serious disruption of the customer process line.

The A.Q.L for this class is 0,40

*** Class C and D major non-conformities**

These non-conformities, despite being not critical, might cause failure or significantly reduce the product intended use.

Depending on the impact, they are classified as major C or major D non-conformities:

- **Class C non-conformities or C major non-conformities**

The A.Q.L for this class is 0,65

- **Class D non-conformities or D major non-conformities**

The A.Q.L for this class is 1,5

*** Class E non-conformities or aspect non-conformities**

These non-conformities reflect a disparity versus specifications, but which do not jeopardize the use of the product.

The A.Q.L for this class is 4

5. Categories of non-conformities

Non conformités	Inspection levels		Non-conformities
	II	S3	
Classe = A ou Critiques A	II	S3	Class = A or Critical A
A = 0 R = 1			A = 0 R = 1
Aiguille	x		Spike
Débris de verre intérieur	x		Adhered glass particle, Loose Glass
Ailette coupante	x		Sharp dangerous fin
Erreur de gravure	x		Incorrect engraving
Mélange de flacons	x		Rogue component
Perchoir/ trapèze	x		Bird swing
Picot intérieur	x		Inside projection
Résistance hydrolytique non conforme aux exigences des pharmacopées européenne et américaine		x	Non-conforming hydrolytic resistance (in reference to European and American pharmacopeia)
Transmission lumineuse non conforme aux exigences des pharmacopées européenne et américaine (verre jaune uniquement)		x	Non-conforming spectral / light transmission (in reference to European and American pharmacopeia - amber glass only)
<u>Pour flacons thermoscellés :</u> Absence d'enduction pour thermoscellage si applicable		x	<u>For heat sealing coated products:</u> Lack heat sealing coating if applicable

Non conformités	Inspection levels		Non-conformities
Classe = B ou Critiques B	II	S3	Class = B or Critical B
<p style="text-align: center;">N.Q.A 0,40</p> <p>Bavure intérieure bague x Bouillon cassant intérieur (1) x Cassé sans morceau de verre x Débris de verre libre Corps étranger intérieur visible x Non-conformité bague avec non-étanchéité (pli sur bague, bague mal rendue) x Déformation grossière x</p> <p>Diamètre corps ou bague > maxi Diamètre Intérieur Col < mini Diamètre ouverture hors tolérance Dimension hauteur > maxi Incisé traversant (*) coupé bague x Incisé traversant (*) bas col x Incisé traversant (*) corps x Incisé traversant (*) fond x Choqué avec perte d'étanchéité x</p> <p>Résistance à la pression interne hors tolérance (si spécifiée). Résistance à la charge verticale hors tolérance (si spécifiée) Recuit non conforme</p>			<p style="text-align: center;">A.Q.L 0.40</p> <p>Neck finish inside over press Internal soft blister (1) Breakage without glass in packaging Lose glass Internal, visible foreign bodies Finish distortion affecting sealing integrity: (Line over finish, Unfilled-Malformed finish) Severely deformed not suitable for processing Body or neck diameter > maxi Bore diameter < mini, Choked neck Neck ID out of tolerance Overall height > maxi Split finish Crack at base of the neck Crack on the body Crack at the bottom Bump check integrity affected</p> <p>Non-conforming internal pressure resistance (if specified) Non-conforming vertical load resistance (if specified) Residual stress</p>
<p><u>Pour produits siliconées :</u> Siliconage non conforme selon MO 8 0003 et MO 8 0004</p> <p>(*) ou glaçure avec perte d'étanchéité</p> <p>(1) Voir annexe 1</p>			<p><u>For siliconized products:</u> Non-conforming siliconization according to MO 8 0003 and MO 8 0004</p> <p>Crack: affecting sealing</p> <p>(1) Refer to appendix 1</p>

Non conformités	Inspection levels		Non-conformities
Classe = C ou majeurs C	II	S3	Class = C or major C
<p style="text-align: center;">N.Q.A 0,65</p> <p>Incisé non traversant bague Incisé non traversant bas col Incisé non traversant corps Incisé non traversant fond Bague ébréchée, étanchéité bonne Bavure extérieure bague Capacité ras bord < mini Déformé bague et col Diamètre contre bague > maxi Diamètre extérieur col > maxi Fond enverré important Paroi mince affectant la solidité Taché intérieur (1) Test choc thermique non conforme</p> <p>(1) Voir annexe 1</p>	<p>x x x x x x x x x x x x x x x x</p>	<p> x x x x</p>	<p style="text-align: center;">A.Q.L 0.65</p> <p>Check in the neck Check at base of the neck Check on the body Check at the bottom Chipped neck finish, sealing integrity non-affected Over press on outside of finish Brimfull Capacity < mini Unfilled finish, warped finish, seal integrity is intact, pinched neck Diameter back ring > maxi External diameter of neck > maxi Severe glazed bottom Thin distribution affecting the strength of the bottle Internal contamination (1) Non-conforming thermal shock</p> <p>(1) Refer to appendix 1</p>

Non conformités	Inspection levels		Non-conformities
Classe = D ou majeurs D	II	S3	Class = D or major D
<p style="text-align: center;">N.Q.A 1,5</p> <p>Affaissé/ basculant Diamètre corps et bague < mini Dimension hauteur < mini Déformé corps</p> <p>Ebréché / écaillé Gravure illisible Larme (1) Pierre (1)</p> <p>Capacité ras bord > maxi Verticalité, bague déportée, bague penchée hors tolérance hors tolérance (voir fiche CETIE DT 15.04)</p>	<p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p>	<p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p> <p style="text-align: center;">x</p>	<p style="text-align: center;">A.Q.L 1.5</p> <p>Rocker bottom Body diameter and neck OD < mini Overall height < mini Sunken side, bulged side malformed shoulder Chipped glass Illegible engraving Knot (1) Stone (1)</p> <p>Brimfull Capacity > maxi Leaner, offset neck; bent neck (see CETIE data sheet DT 15.04)</p>
<p><u>Pour flacons thermoscellés :</u> Manque d'enduction pour thermoscellage</p> <p>(1) Voir annexe 1</p>		<p style="text-align: center;">x</p>	<p><u>For heat sealing coated products:</u> Insufficient coating of sealing complex for heat-sealing on the neck finish</p> <p>(1) Refer to appendix 1</p>

Non conformités	Inspection levels		Non-conformities
Classe = E ou non conformités d'aspect	II	S3	Class = E or aspect non-conformities
N.Q.A 4			A.Q.L 4
Bague encrassée	x		Rough finish
Bouillons dans la masse (1)	x		Hard Blister (1)
Bouillons de surface externe (1)	x		External soft blister (1)
Puce	x		Seed
Calciné	x		Surface check
Arraché, plis creux (1)	x		Tear, hallow fold, pressure fold (1)
Choqué sans perte d'étanchéité	x		Bump check non-impacting integrity
Collé non coupant	x		Stuck glass without sharp edges
Corde/ griffure	x		Cord, feeder streak
Ondé	x		Wavy cord
Fond enverré	x		Glazed bottom
Frisé (1)	x		Washboard, brush marks (1)
Martelé	x		Hammered effect
Point noir (1)	x		Black spot (1)
Pli (1)	x		Lap mark body fold or loading mark
Piqué encrassé	x		Pitted surface, orange peel
Raccord moule	x		Blank seam, mismatched neck ring seam, heavy mould seam
Raccord fond ébaucheur déporté	x		Swung baffle
Rayé	x		Scratch, Scuff
Répartition irrégulière, talon	x		Heel tap
Taché extérieur (1)	x		External contamination (1)
Marque de ciseaux	x		Shear mark
<u>Pour produits siliconées :</u>			<u>For siliconized products:</u>
Traces blanches de silicone	x		White traces of silicone
Voile de siliconage	x		Bloom of silicone
(1) Voir annexe 1			(1) Refer to appendix 1

6. Dispute settlement

This chapter details the procedure for accepting or rejecting deliveries.

6.1. Incoming inspection

Accepting or rejecting of the vials and bottles are based on statistical sampling results as described in § 4.1.

6.1.1. Acceptance

Deliveries that pass the inspections as defined in these Specifications are accepted.

Within a continuous improvement approach, when a delivery sample has a total number of faulty units below the rejection threshold, and the customer still wants to draw SGD Pharma's attention to the non-conformities /imperfections observed, an "annotated acceptance" is issued for delivery.

When a delivery sample has a total number of faulty units above the acceptable quality level as defined in the Specifications and if the customer deems that, exceptionally, the nature of the non-conformities or their effects on the packing process and brand image will not be too serious, this delivery can be accepted under concession.

6.1.2. Rejection

When the delivery does not comply with the standards defined in the Specifications, it is rejected (except in the case described in § 6.1.1 where the customer accepts the delivery under concession). A claim should be forwarded to SGD Pharma.

SGD Pharma reserves the right to carry out its own inspection.

SGD Pharma shall be advised in written. The necessary information (see § 6.3) and contentious samples should be sent to SGD Pharma as soon as possible along with the relevant traceability elements (pallet labels, certificate of compliance).

6.2. On the customer processing / packing line

This procedure relates to batches used on the customer processing/packing line without systematic delivery inspection.

In the event of an incident on the processing/packing line attributable to the bottle, the batch compliance to the Specifications should be verified.

The customer should carry out a statistical inspection in compliance with the Specifications on the remaining empty bottles from the same delivery.

If it is not possible to carry out this inspection, the percentage of non-conformities required to assess compliance with the Specifications shall be calculated on a number of bottles equal to the sample number of finished products that the customer must inspect to validate its own production.

SGD Pharma recommends a final statistical inspection approximately every two hours.

If the non-conformities are found during 100% inspection on line, referred to the table 7 of ISO 2859 to make a link with the AQL.

In the event of a claim, the procedure for returning the stock of empty bottles and processing them in order to reach the required standards is the same as that set out in § 6.1.2.

6.3. Claims procedure

To handle a claim, the customer must supply to SGD Pharma the following information:

For every complaint:

- Product reference and batch number
- Impact for customer
- Non-conformities description with pictures or samples
- Type of non-conformity (Critical, major, minor) and consequence on the filling line
- Delivery note, Invoice reference or Delivery date
- Samples (10 samples per non-conformity if possible).
- Quantity with non-conformity or non-conformity rate
- Total quantity of the batch (delivered)
- When the non-conformity has been observed:
 - at receiving:
 - at incoming inspection control:
 - during production:
 - other (please specify)
- Requested actions and lead-time constraints

Optional, but very important for traceability:

- Customer Complaint number
- Pallet labels
- Cavity number

In case of packaging/ transport issue:

- Quantity (vials or packs)
- Positions of the damaged packs on the pallet
- When it has been detected (receiving/incoming inspection)

7. Inspection methods

7.1. Dimensional inspection

This inspection is made using appropriate measurement apparatus (sliding calliper, comparator, etc...) or dimension gauges.

7.2. Capacity control

The capacity tolerances are defined on the drawing of each bottle.

Brimfull or gauge line capacity are measured by weighing (difference in weight between the bottle filled with water and the empty bottle).

7.3. Annealing

Annealing tension is checked using ASTM Standard C148. The delay should not exceed 18 nm per mm of glass thickness.

7.4. Hydrolytic resistance

Hydrolytic resistance is checked using the methods described in the current European and American Pharmacopoeias.

7.5. Light transmission of amber glass

Light transmission is checked using the methods described in the current European and American Pharmacopoeias.

7.6. Arsenic

Arsenic is checked using the methods described in the current European and American Pharmacopoeias.

7.7. Strength tests

If specified, internal pressure resistance is checked using ISO 7458 Standard (AGR's « Ramp Pressure Tester » measures in compliance with this standard).

If specified, vertical load resistance can be measured using ISO 8113 standard.

7.8. Resistance to thermal shock test

Resistance to thermal shock is measured using ISO 7459 standard (limits established according to the type of glass).

8. Validity of the specifications

Once signed by both parties, the customer and SGD Pharma, the present Specifications shall be considered valid without any time limitation

The Specifications may not be modified without the approval of both parties.

If no specific agreement is concluded with the client, our standard aforementioned specifications apply.

9. Appendices

Appendix 1: Maximum size of acceptable non-conformities / imperfections in standard choice of Vials and bottles for oral and nasal application

Appendix 2: Pallet label

Appendix 3: Certificate of Quality

Appendix 4: Summary of changes

Appendix 1

Maximum size of acceptable non-conformities / imperfections in standard choice of Vials and bottles for oral and nasal application

In case of an elongated blister, the dimension to be considered should be the average measurement = (length + width)/2.


Standard
Choice
SGD Pharma

Non-conformites / Non-conformities		Choix / Choice I	Choix / Choice II	Choix / Choice P	Choix / Choice III
Bouillon dans la masse	Blister	1,3 mm	1,5 mm	1,8 mm	2,5 mm
Bouillon de surface externe	External skin blister	0,8 mm	1,0 mm	1,5 mm	2 mm
Bouillon creux externe	External Soft Blister				
Bouillon de surface interne	Internal skin blister	0,8 mm	0,8 mm	0,8 mm	0,8 mm
Bouillon creux interne	Internal Soft Blister				
Larme	Knot	0,8 mm	1 mm	1,5 mm	2 mm
Pli corps / arraché	Body fold or lap / tear	1 cm	1,5 cm	2 cm	2,5 cm
Point noir intérieur	Black spot internal	0,5 mm	0,8 mm	1 mm	1,3 mm
Frisé	Wash Board	1 cm ²	1,5 cm ²	1,8 cm ²	2 cm ²
Taché intérieur	Internal Dirt	0,5 mm	0,8 mm	1 mm	1,3 mm
Taché extérieur	Exterior mark	0,5 mm	0,8 mm	1,0 mm	1,5 mm
Pierre/inclusion	Stone/inclusion	0,8 mm	1 mm	1,3 mm	1,5 mm

Appendix 2 Pallet label

4 pallet labels

- Sequence number of pallet
- Place of manufacture
- Item # (SGD Pharma & Customer)
- Batch #
- Dimension handling unit
- Date
- Pallet #
- Customer Barcode



The pallet label contains the following information:

- Sequence number of pallet:** 10027885345
- Place of manufacture:** SGD S.A. Saint Quentin La Motte, Rue Edle, 69860 ST QUENTIN LA MOTTE CROIX AU, FRANCE
- Item # (SGD Pharma & Customer):** 00772 48 036
- Batch #:** N 155810
- Dimension handling unit:** S
- Date:** 12 JUL 2016 10:30
- Pallet #:** 1
- Customer Barcode:** (00)531402410027885345

Appendix 3 Certificate of Quality

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CERTIFICATE OF QUALITY

The 29.08.2016 / 1004
Customer

SGD S.A.
Public limited company with capital of 85,000,000.00 EUR
Nominale Trade and Companies Register N°8982 812 888
VAT ID : FR 29 852 812 888
Head Office and Sales Departments : 148bis Terrasse Belleval - 92807 Puteaux - France
Phone : +33(0)1 40 90 36 00 - Fax: +33(0)1 40 90 36 01
Postal address : 148bis Terrasse Belleval - 92807 Puteaux Cedex - France

SGD Product Code 00772 48 036 ANTIBIOTIQUE 60
SGD Drawing N 1436 IN Treatment Cold TYPE I CLEAR GLASS
Run Number N 1559103 Manufacturing Date 04.11.2016 to 17.11.2016
Quantity per Pallet 6400 Production Site SAINT QUENTIN France

We, SGD S.A., hereby certify that the above referred bottles have been tested and are in conformity with:

THE SPECIFICATIONS IN FORCE

THE HYDROLYTIC RESISTANCE:

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force

Hydrolytic Resistance testing - Grain - is done at least once per year.

ABSENCE:

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force

As testing is done once per year.

GLASS CHARACTERISTICS

	UNIT	Specifications		Results		
		Min	Max	Min	Max	Avg
WTDRO-RESISTYP-PWDRS/TP	ml	0,10	0,25	0,05	0,25	0,05
WTDRO-RESISTANCE SURFACE	ml	0,10	0,25	0,11	0,12	0,00
AMBIQUE	ppm	0,10	0,05	0,05	0,05	0,00
EXTRINSICAL PROPERTIES	bar	0,05	11,40	30,60	23,65	5,47
USP OPTICAL LEAK	ml/100	200,00	150,00	1,540,00	602,63	348,33
USP SEAL LEAK	Drop	60,00				Conforme
LEAKING						Conforme

Quality Manager
Emmanuel Lottin

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CERTIFICATE OF QUALITY

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LEAKING						Conforme

Quality Manager
Emmanuel Lottin

Appendix 4

Summary of Changes

Section	Changes
-	Update of SGD Pharma's logo Update of document's title AQL: Acceptance Quality Limit Oral instead of drinkable Change of the word template
Introduction	'Quality Management System' instead of 'quality assurance system' – 'General' added to 'Specifications'
3.2	Translation of the title becomes: 'Production environment/ Clean Room' Part 1 of ISO Standard 14644 added
3.4	Clarification of this section: 'The raw or sourced materials or reagents used in the manufacturing process are not derived from animals or humans and thus comply with EMA/410/01.' Regulation EMA/410/01 added
3.5	Last sentence suppressed
3.6	First sentence suppressed
3.7	'The product is sitting on' suppressed + mention of the ISPM 15 norm
3.8 & 3.9	Divide section shelf life and storage in two 'The minimum...one year' suppressed 'Under normal....one year' added – 'Height 5,6 meters' instead of 'Height of 5 meters' 'The minimum storage period under normal European weather conditions will be around one year' modify by 'Under normal European weather conditions, storage period can be around one year'
3.10	Add a section about the ready for use statement
3.11	'If the customer notes any damage to pallets delivered, SGD recommends raising standard reserves on the delivery notes when taking delivery.' Suppressed (to be put in the Standard QA)
3.12	'Number of modules' added 'The production line' suppressed
3.13	'The final.... (dedicated area)' suppressed Last sentence modified by: 'Each SGD Pharma shipment for a given item number and a given SGD Pharma P/O number constitute an in-coming inspection batch.'
3.15	Change Control section suppressed
3.16	Cleanliness section suppressed
3.17	Handling quality records section suppressed
4.1	Remove % from AQL
4.1	Correction in the sheet of sampling S3 + Add lower AQL and remove 6.5
5	Alignment on the PDA report 43 Add "checks" non-conformities Add Defective siliconization non-conformities
6.1.1	'Within a continuous improvement approach' added 'under concession' instead of 'with a derogation'

Section	Changes
6.1.2	'under concession' instead of 'with a derogation' 'in written' instead of 'by fax or e-mail' 'Two courses of action are possible...measures' suppressed
6.2	'If the non-conformities are found during 100% inspection on line, referred to the table 7 of ISO 2859 to make a link with the AQL.' added
6.3	Claim Procedure section aligned with the Standard Quality Agreement
6.4	Claim Response period section suppressed
8	Product Related Services section suppressed totally (8.1 8.2 8.3 and 8.4) and replaced by Validity of Specifications section
10	Audits section totally suppressed
Appendix 1	Add of all SGD Pharma choice
Appendix 2	New Label with new LOGO added
Appendix 4	Summary of the change added