Defect Library of Blow-Fill-Seal Containers

Editor

Dr. Heino Prinz – Rommelag Engineering

Contributors

Dr. Michael Spallek, Roland Sauter, Michael Schultes, Reto Habermacher, Helmut Bauer – Rommelag Engineering

Dr. Jan Bornhöft, Dr. Martin Haerer, Diego Danz – Rommelag CMO

Dagmar Nachtigall – Rommelag Pharma Service

1 Content

2 Versions Control

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3 Preface

The 2020 update of the EU-GMP-Annex 1 (European Comission, 2020) recommends the documentation of container defects used for pharmaceutical packaging. For glass packaging this has been accomplished many years ago, under the umbrella of the Parenteral Drug Organization (PDA). A defect library covers glass containers like ampoules, cartridges, and vials. This library contains descriptions and pictures together with a criticality assessment and is organized under the process and handling aspects of the associated risks.

Based thereon a similarly structured document has been created to cover blow-fill-seal (BFS)-containers.

It applies a classification scheme to systemize the defects along with the positions of their occurrence at the wide variety of the container forms and it capture the different types of defects together with their criticality.

The compendium is divided into three parts. The first part gives the definitions of the individual parts of BFS containers used throughout this compendium as well as the general description of the most important process parts and functions.

The second section generally describes the defect in its process environment or its specific occurrence within the BFS process respectively. In this Part also, the impact of the defects with respect to possible patient or product risks, i.e. their criticality is listed. The systematic divides these defect types into BFS Process defects, and there into extrusion related faults, shortcomings within the formation and filling process and secondary handling deficiencies like punch or marking flaws.

The third part, the library section then shows the specifics of those defects with the help of pictures along with a tabular summary of their most prominent parameters like occurrence position and Designation etc. In addition, this part classifies into the two groups of BFS containers the large volume containers, like bottles used for large volume parenterals (LVP), disinfectants or rinsing solutions and small volume containers, like ampoules used for ophthalmics, inhalation drug products or small volume parenterals (SVP).

4 Part One: Definitions

4.1 Container types and definitions of their parts

Container Type or part	Abbreviation/ Synonyms	Description
Block	Card	A multitude formation of single containers. Usually the BFS creates larger Blocks which are separated into smaller blocks/cards or singles.
Bottle		Container with a total volume of 50 ml or more, e.g. for large volume parenterals (LVPs)
Expiry Date Engraving	Exp	The engraving of a specific alphanumeric string which identifies the production Date of the drug product. Most often on Flags
Flag		Bottom part of the container which is formed like a flag. Often used for Labelling, Printing of Lot/Exp markings
Hanger		Functional Part on the bottom of IV Bottles to fix the bottle on a stand in upside down position for infusions.
Large Volume Parenteral container	LVP	Bottle-like or bag-like container used for large volume parenterals.
Lot Identification engraving	Lot	The engraving of a specific alphanumeric string which identifies the production lot of the drug product. Most often on Flags
Luer		Specifically formed shape of head area to ensure tight connections to ports, syringes or needle ports. See also ISO 80369
Luer Lock		A Luer with additional function to interlock the connection to the port, see also ISO 80369
Neck	Shoulder	The part of the container that describes the transition between head and body. Shoulder is mostly used with bottles
Port	Needle Port, Hub, access port	Describes the connectivity or access function element of the container to infusion sets (ISO 8536) or tubes or needles

Small Volume Parenteral container	SVP	Ampoule-type container used mainly for injectable drug formulations.
Twist Off tab		Upper part of the head of an ampoule type container formed as a tab. Is used as handle to open the container; in rare cases also found in bottles
Vial Type Design	Vial	An Ampoule Design with a flat and circular Footprint. Similarities to glass vial shapes.
Wall		Side areas of the container body

Table 1 Definitions and Naming conventions of BFS containers

4.2 Process parts and functions

BFS processing covering rotary and shuttle machines is extensively described by Oschmann et al. 1999 and by the BFS International Operators Association 2016 and therefor only will be summarized in this document.

4.3 Typical properties and designations for BFS-Container (non-defects)

BFS container typically extruded from polyolefins like LDPE, HDPE and PP are usually produced in two major forms as ampoules for small volumes (0.5ml to 50ml) and as bottles for larger volumes (from 50ml up to 2000ml).

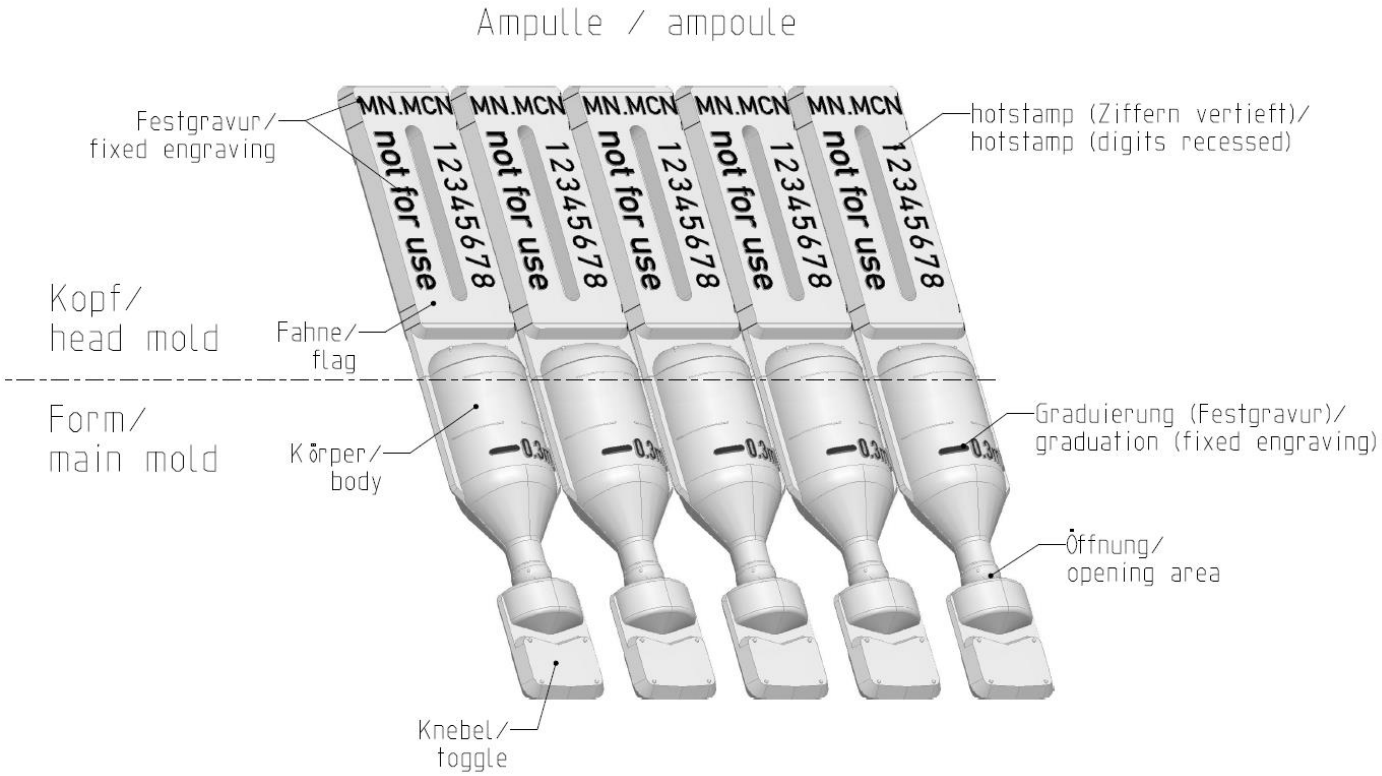


Figure 1 Drawing of a BFS Ampule Card

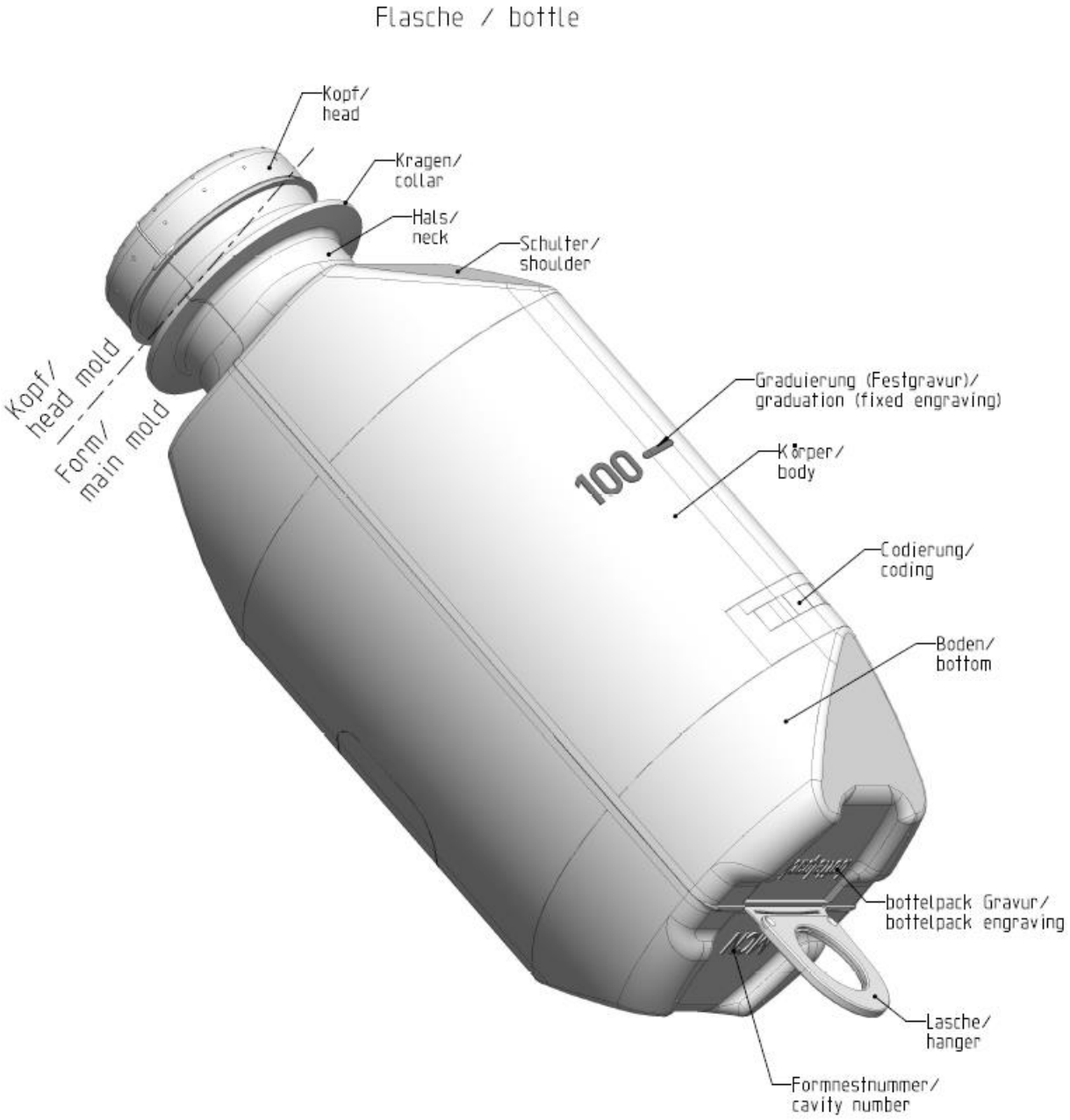
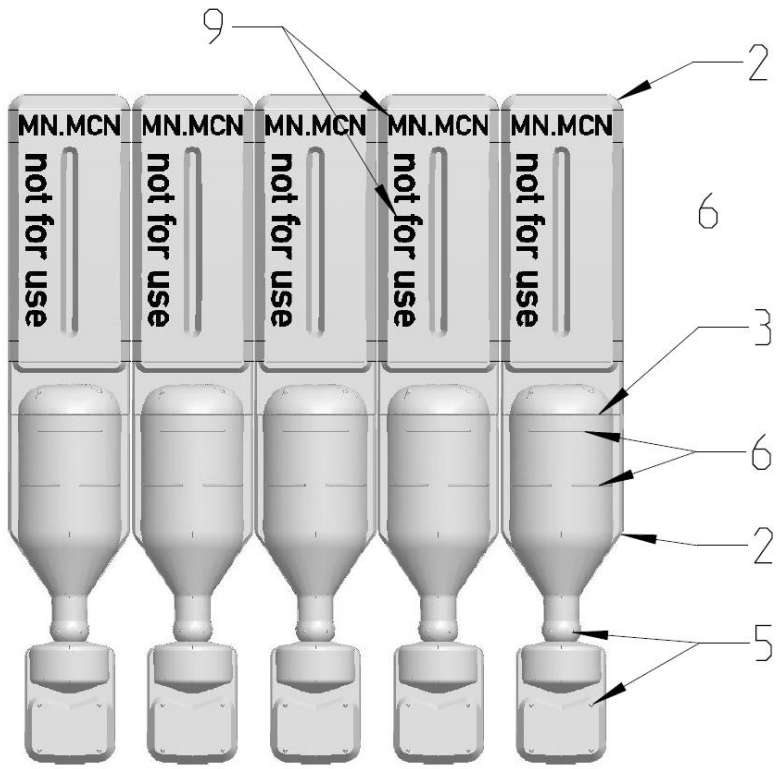
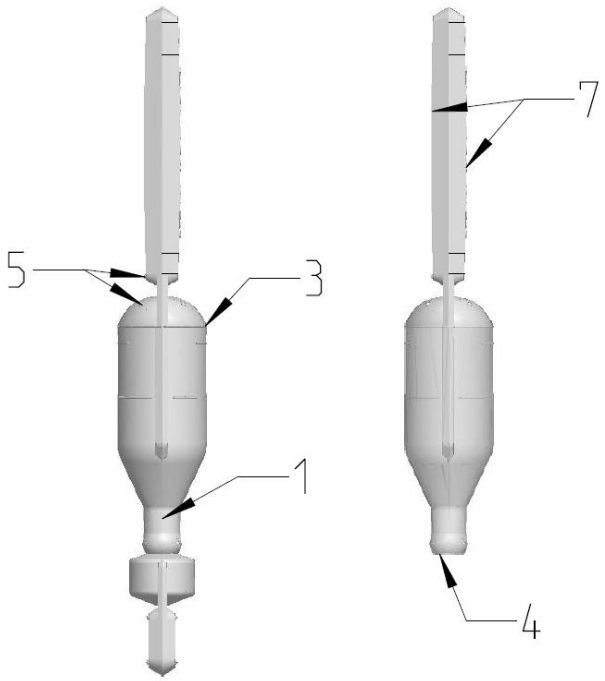


Figure 2 Drawing of a BFS Bottle

The names and definitions of the parts of these containers are given in the tables below.

	2 Edges (different for PE and PP) 3 Offset Head/Mould 5 Mark of vacuum holes 6 Vacuum slit; separation ledge 9 Engraving
	1 Separation Line 3 Offset Head/Mould 4 Twist-off – Breakpoint 5 Mark of vacuum holes 7 Flag

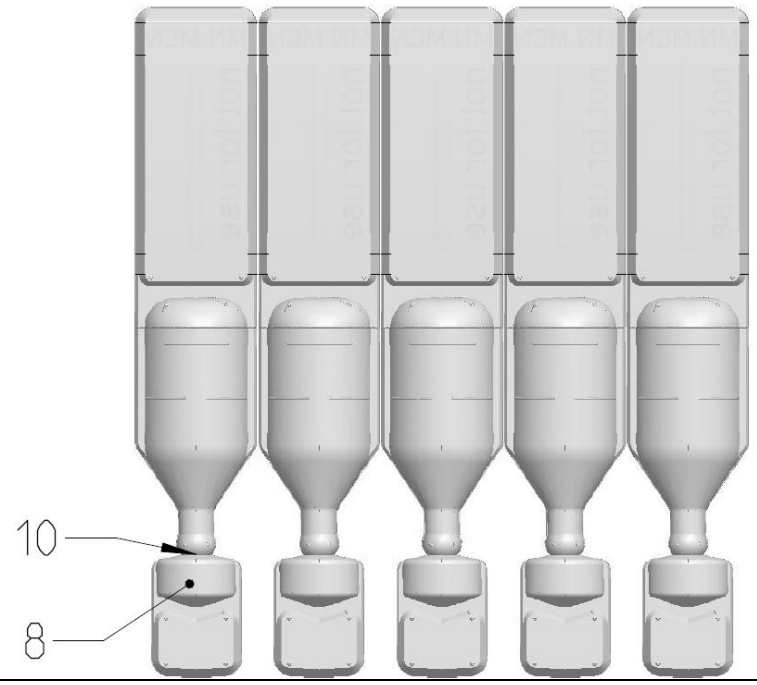
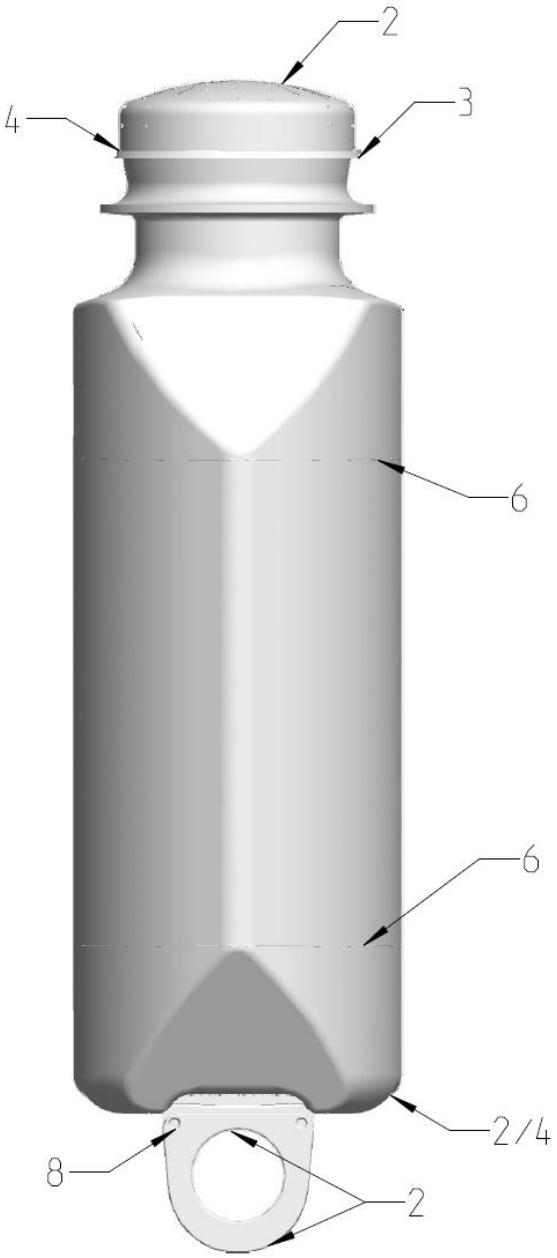
	8 Reclosure 10 Twist-off

Table 2 Part names and definition of BFS ampoules



2	Separation line
3	Head/Mould offset
4	Burrs
6	Mark of vacuum holes
8	Hanger

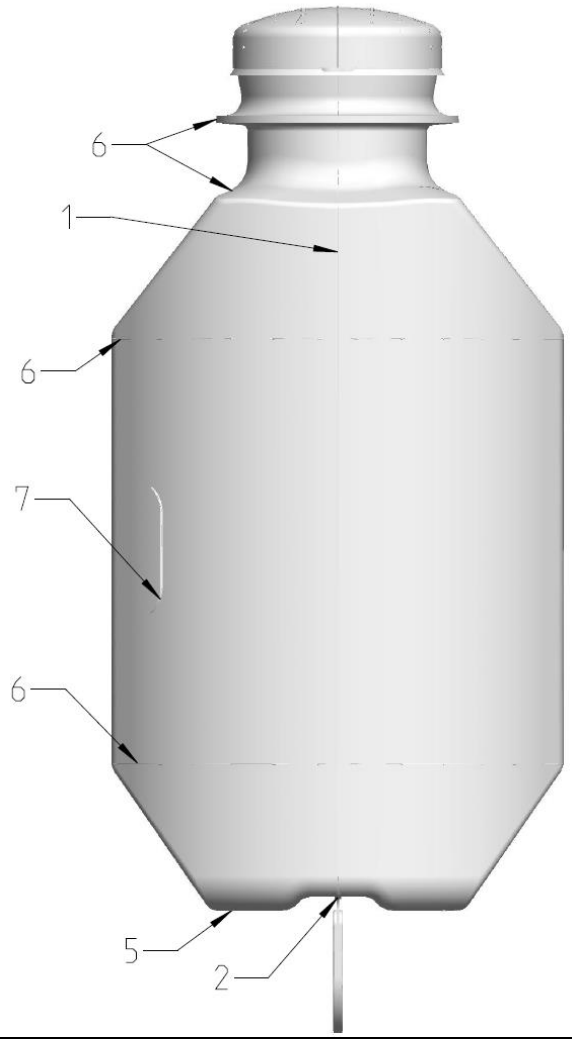
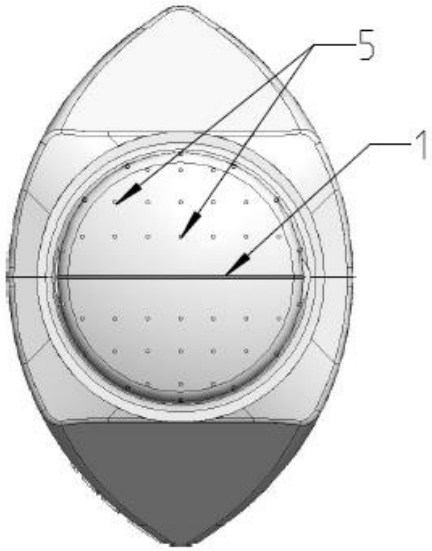
	1 Separation line 2 Edges 5 Mark of vacuum holes 6 Vacuum slit/separation ledges 7 Mark of volume displacement
	1 Separation line 5 Puncture zone with marks of vacuum holes

Table 3 Part names and definition of BFS bottles

5 Part Two Defects in BFS

In the following descriptions we will picture out some of the defects that could arise during BFS-Processing including the separation of single containers from a block, e.g. by punching. It does not claim completeness but gives a good overview of the challenges a production process must cope with.

5.1 Defect types and criticality

The following table summarizes the defect types with their manifestations or designations respectively.

Defect Type	Manifestations
Deformation (handling)	General Deformation
	Scratches
Deformation (moulding)	Collapsed Twist off
	Dent
	Form defect
	Function Defect
	General Deformation
	Markings
	Inflated flag/hanger
	Mould offset
Engraving	Illegibility
Excess Material (inside)	Excess Material
	Folding
	Plugged
Excess Material (Outside)	Folding
	Protrusion
Lack of Material	Cut
	Hole external
	Hole internal (unwanted connection between internal cavities)
	Thinned area
Particles	Embedded particles, e.g. Black Spots
	Crystallization
	Non embedded e.g. free-floating Particles
	White Spots
Functional Defect	Deformation defect after opening
Other	Deflashing
	Thread Position
	Vacuum
	Puncture
	Mechanical Deformation
	Alignment
	Leaking
	Extrusion
	Trapped Air
	Scratches
	Transparency
	Shadows

Table 4 Defect Types and Definitions of their manifestations of BFS containers

For the container manufacturer the criticality denomination of defects goes along with the Defect Listings in

"Quality Assurance of Pharmaceutical and Cosmetic Packaging Materials–Section: Defect Evaluation List for Blow-moulded Plastic Containers" (see 7),

but for the Pharmaceutical Industry another definition is related to the effects on patient safety and functionalities. Therefore, we use the definition of minor, major and critical as follows.

- Minor: More or less a cosmetic defect.
- Major: could become a functional defect.
- Critical: could affect patient health (i.e defect can cause leakers and therefore a sterility issue or external contamination of product i.e. free particles)

5.2 Extrusion process

Starting from melting of plastic granulates, the extrusion process and the formation and handling of the parison is a potential source of defects. A major topic here can be the introduction of foreign matter in or on the granulates and carbonized material within the parison wall that might end up in black spots embedded in the container side walls.

5.3 Parison control

Another source of defects in the extrusion process might result from misalignment and guiding of the parison. This might lead to crinkles and folding of the container wall.

Also, uneven parison thickness might introduce excess or lack of material. It might introduce a closure clogging in the opening or cause a cloudy structure in the container walls. Thin spots on the container edges might arise from lack of material at these positions.

5.4 Moulding Process

Especially defects arising from the moulding process (i.e. by blow and/ or vacuum forming) might lead to functional failures or improper formed containers which may also affect the subsequent processes like punching or causing handling errors within downstream processes.

Also, a moulding defect might cause scratches or folds. Those defects can become severe and therefore critical defects, because they might cause potential leakers also way apart from the production time. A similar type of defect arises from the punch handling (see later in this paragraph). Additionally, the correct alignment of mould and head mould is critical to the process.

A very special defect is based on vacuum inconsistency in the forming process caused either by vacuum control failure or blocked vacuum holes inside the mould.

The mould defects can vary with geometry and form, and therefore a wide variety of defect presentations can occur.

Especially in shuttle machines a leaking cooling system may create improper sealed and leaking ampoules.

Deformation errors are usually incorrectly formed body, head and shoulder areas or dents in the shoulder. The result is an ampoule not correctly formed on the bottom. Additionally, dash shaped marks along the head of an ampoule or bottle presumably caused by droplets from the filling tube might appear.

Also, the thread formed on the neck of the bottle might be insufficiently shaped.

Some forms like bellow shaped containers may have inclined bellow structures.

5.5 Filling Process

During filing prominent example of defects are caused by mandrel contact with the parison. This leads to two defect types one is causing leaks at the contact position the other creating excess material inside the container around the contact position by relocating warm and soft plastic material along the mandrel movement.

In some cases, also paraffin is accumulating outside the mandrel and finally dropping down into the container causing white spots on the inner surface.

Extensive overfilling of a container might cause subsequent failures causing insufficient sealing, and therefore leakers. Also, non-embedded (free) particles e.g. from tubing or gasket material might be caused by improper filling processes.

Foaming products may cause leakers in the sealing area. Viscous products can create filling volume issues and variances due to inappropriate chosen machine settings.

5.6 Particles

Particles usually manifest as embedded particles within the container walls or as free-floating particles in the liquid. Whereas the embedded type is most likely either contamination of the raw material or carbonized polymer due to overheating. The free-floating particles could arise from metal parts or gasket material from the filling path or from the cutting process in shuttle machines. When using the closed parison BFS-technology free floating polymer particles are very unlikely to occur. Due to the non-brittle nature of the BFS-polymers the occurrence of free polymer-particulate in a container is very low.

5.7 Separation/Punching process

Typical punch defects are scratches of the container due to improper guiding and/or clamping during the separation process. They are mostly cosmetic and rarely functional defects and therefore classified as of minor defect. Nevertheless, incorrect punch settings can also cause leaking containers which are critical defects.

5.8 Mechanical Handling and other defects

Other defects could result from handling interactions and other contaminants like abrasion particle usually introduced through the machine process. Especially scratches are common when pick and place systems are involved in downstream processes after the BFS process where the outside of the container is still warm and therefore soft.

Furthermore, the encoding defects coming from “Hot Stamping” or “Laser Engraving” might be seen. They are ranging from reduced legibility to missing parts or letters.

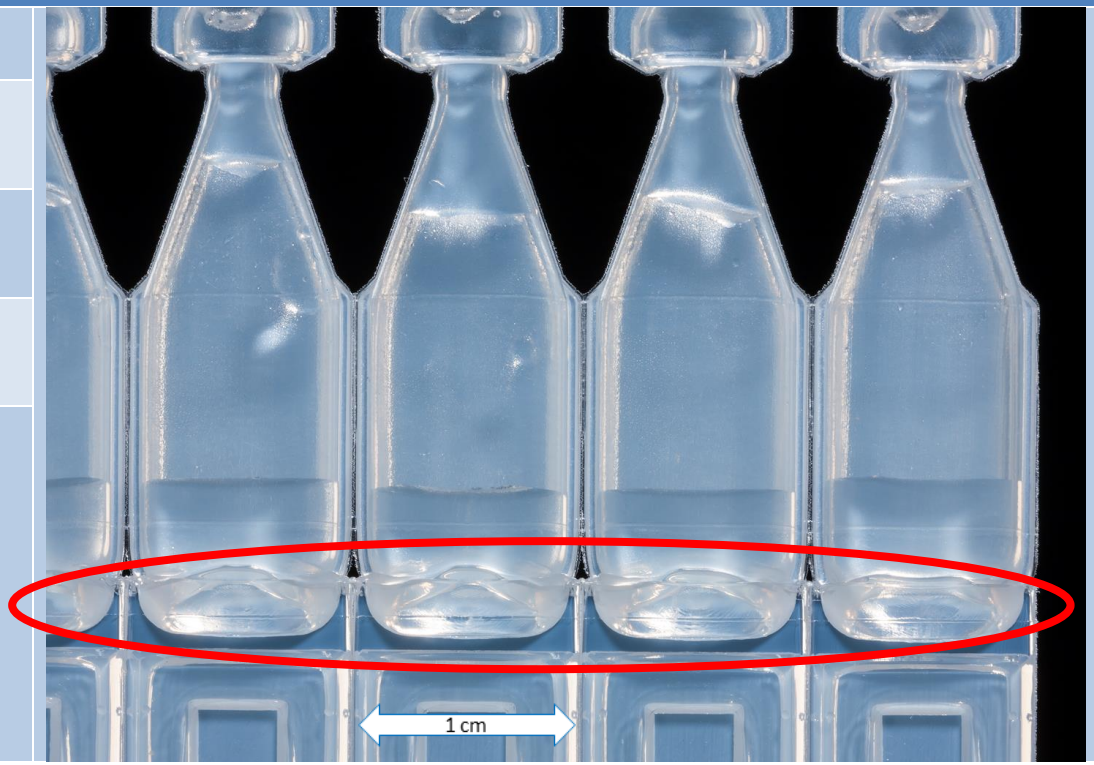
6 Part three: Defect Library (sorted by defect type)

6.1 Excess Material (inside)

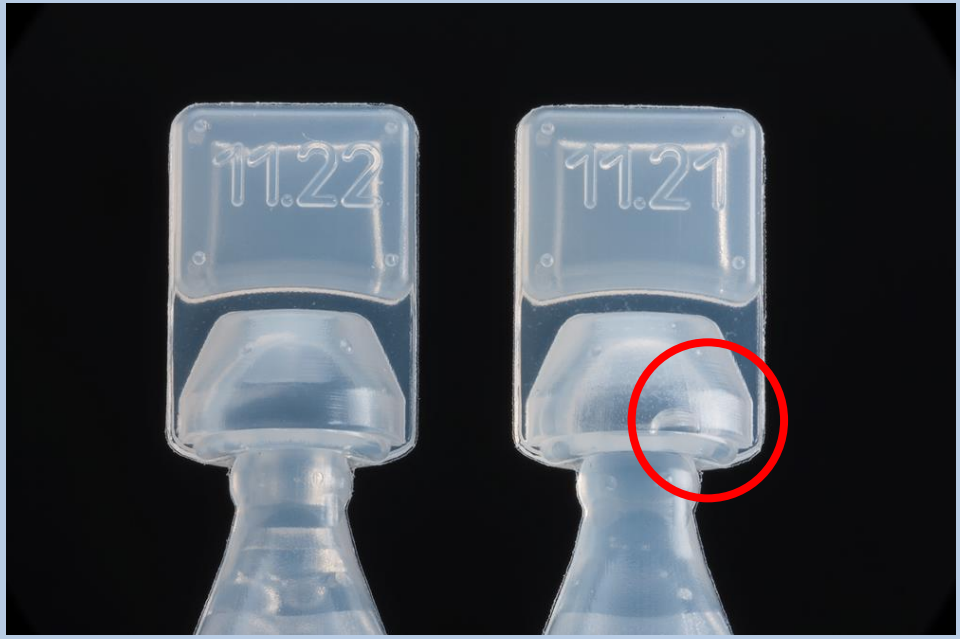
RE-0091	Description	Picture
Defect designation	Folding	 
Defect occurrence (process)	Parison Control	
Defect Position (Container)	Twist-off tab	
Defect Type	Excess Material (inside)	
Criticality	Minor	

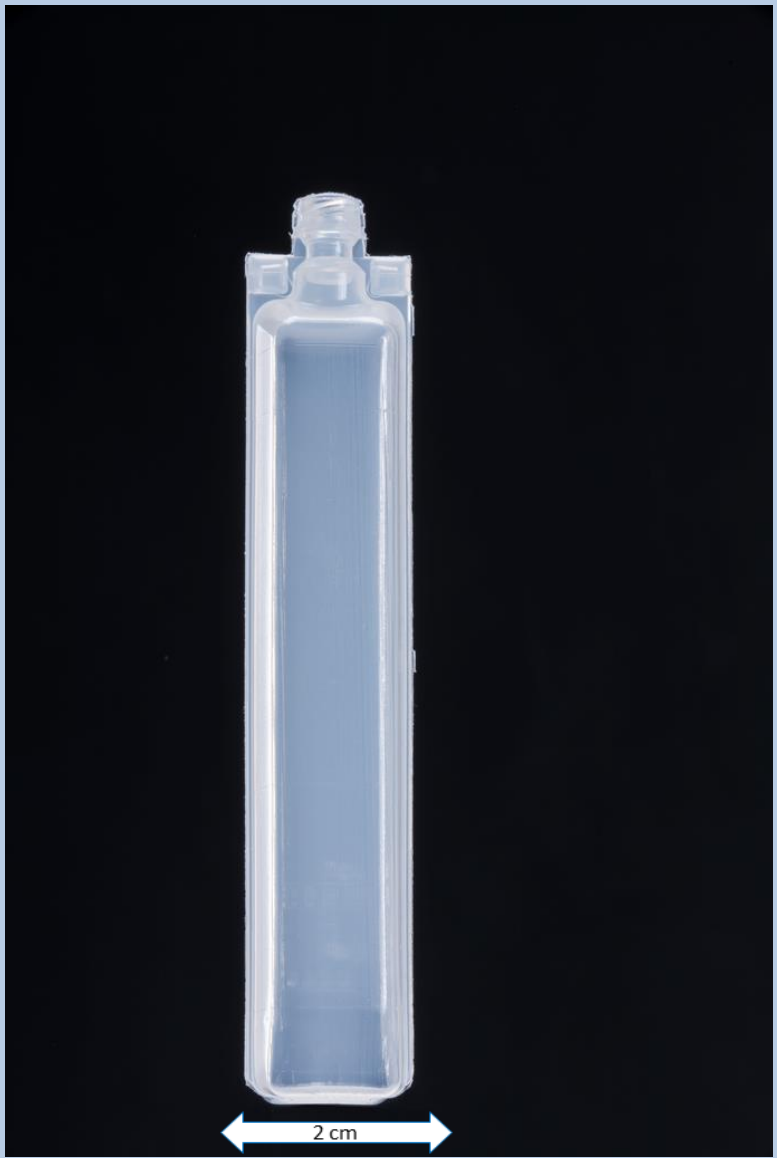
RE-0141	Description	Picture
Defect designation	Excess Material	 
Defect occurrence (process)	Parison Control	
Defect Position (Container)	Neck	
Defect Type	Excess Material (inside)	
Criticality	Major	

RE-0101	Description	Picture
Defect designation	Excess Material	 
Defect occurrence (process)	Parison Control	
Defect Position (Container)	Neck	
Defect Type	Excess Material (inside)	
Criticality	Minor	

RE-0230	Description	Picture
Defect designation	Excess Material	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body/Flag	
Defect Type	Excess Material (inside)	
Criticality	Minor	

RE-0234	Description	Picture
Defect designation	Plugged	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body/Flag	
Defect Type	Excess Material (inside)	
Criticality	Major	

RE-0247	Description	Picture
Defect designation	Excess Material	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Twist Off	
Defect Type	Excess Material (inside)	
Criticality	Minor	

RE-0278	Description	Picture
Defect designation	Excess Material	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Twist Off	
Defect Type	Excess Material (inside)	
Criticality	Minor/Major (when calibrated Luer)	

6.2 Excess Material (outside)

RE-0121-1	Description	Picture
Defect designation	Folding	 
Defect occurrence (process)	Parison Control	
Defect Position (Container)	Body	
Defect Type	Excess Material (outside)	
Criticality	Minor	

RE-0085	Description	Picture
Defect designation	Protrusion	 
Defect occurrence (process)	Punching	
Defect Position (Container)	Twist Off	
Defect Type	Excess Material (outside)	
Criticality	Minor	

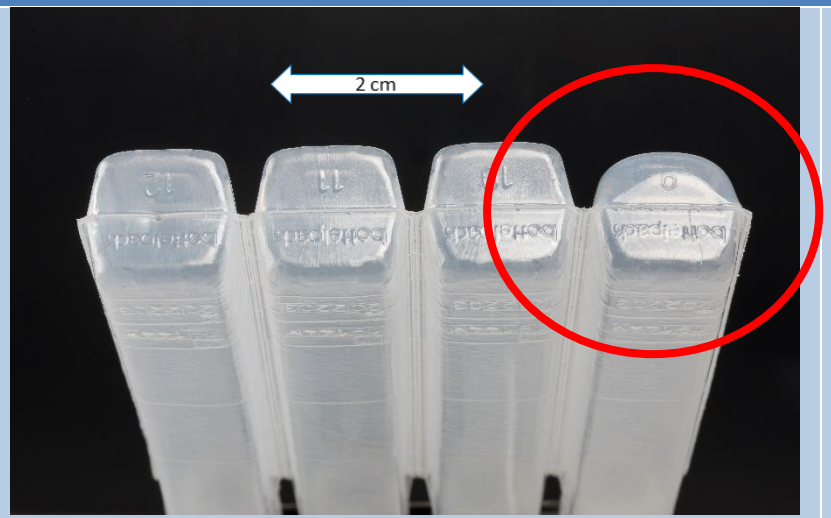
RE-0113	Description	Picture
Defect designation	Protrusion	 
Defect occurrence (process)	Punching	
Defect Position (Container)	Twist Off	
Defect Type	Excess Material (outside)	
Criticality	Minor	

RE-0103	Descritption	Picture
Defect designation	Protrusion	 
Defect occurrence (process)	Punching	
Defect Position (Container)	Twist Off	
Defect Type	Excess Material (outside)	
Criticality	Minor	

6.3 Deformation (moulding)

RE-0075	Descritption	Picture
Defect designation	Function defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	head	
Defect Type	Deformation (Moulding)	
Criticality	Minor/Major if cap function is affected	

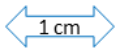
RE-0083	Descritption	Picture
Defect designation	Form Defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Head	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0097	Description	Picture
Defect designation	Form Defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Bottom	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0001	Description	Picture
Defect designation	Form Defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	head	
Defect Type	Deformation (moulding)	
Criticality	Minor/Major if cap function is affected	

RE-0116	Description	Picture
Defect designation	General Deformation	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Neck	
Defect Type	Deformation (moulding)	
Criticality	Minor	

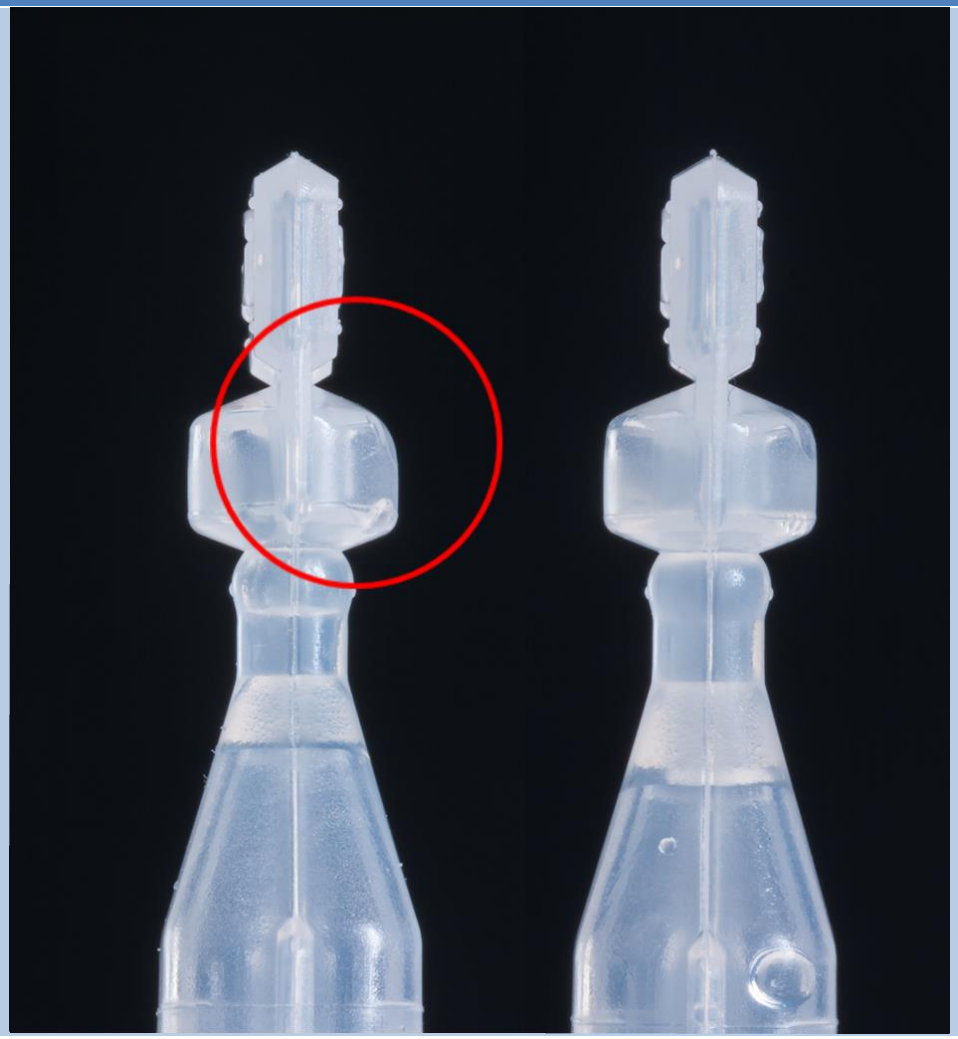
RE-0087	Description	Picture
Defect designation	General Deformation	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Neck	
Defect Type	Deformation (moulding)	
Criticality	Major (reclosure function affected)	

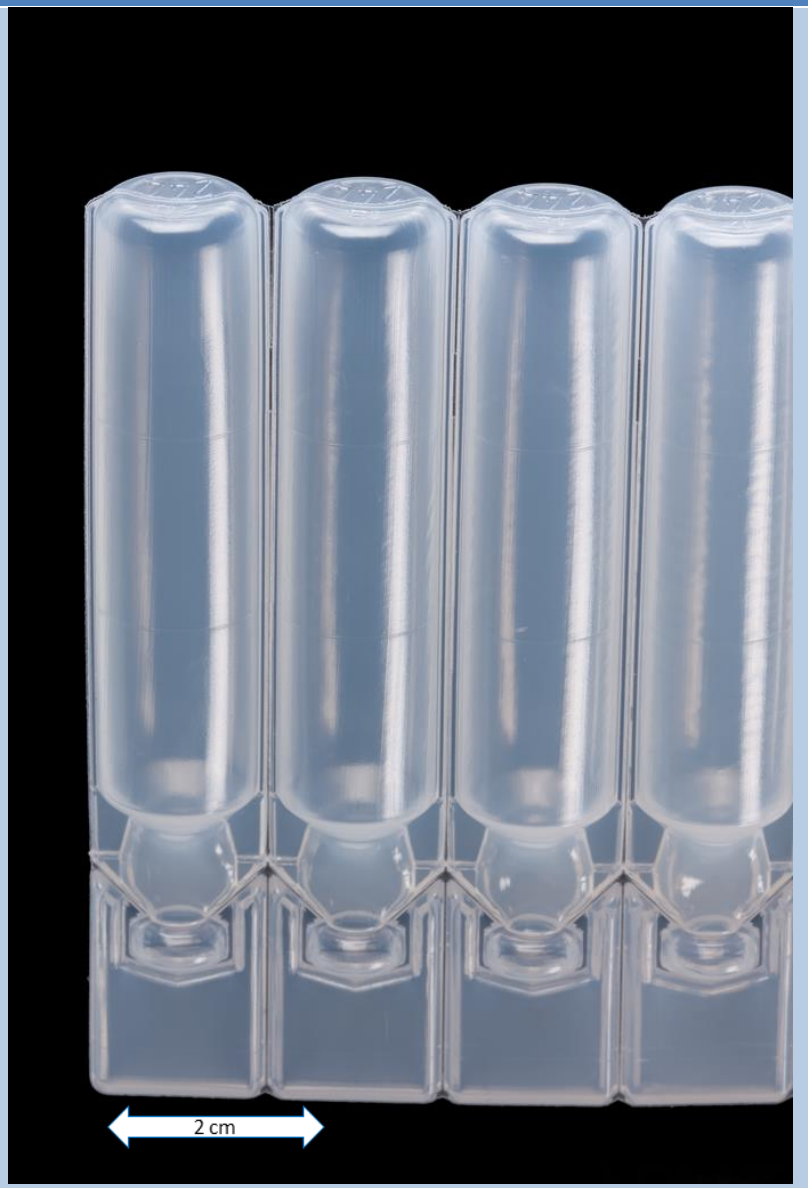


RE-0123	Description	Picture
Defect designation	Form Defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Head	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0124	Description	Picture
Defect designation	Collapsed Twist Off	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Head	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0139	Description	Picture
Defect designation	Form Defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Shoulder	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0224	Description	Picture
Defect designation	Form Defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Twist Off	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0237	Description	Picture
Defect designation	Form Defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body	
Defect Type	Deformation (moulding)	
Criticality	Minor/Major if self-standing is affected	

RE-0242	Description	Picture
Defect designation	Form Defect	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Bottom	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0121-2	Description	Picture
Defect designation	Excess Material	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Head	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0121-3	Description	Picture
Defect designation	Inflated Hanger	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Hanger	
Defect Type	Deformation (moulding)	
Criticality	Minor/Major if hanger break force is affected	

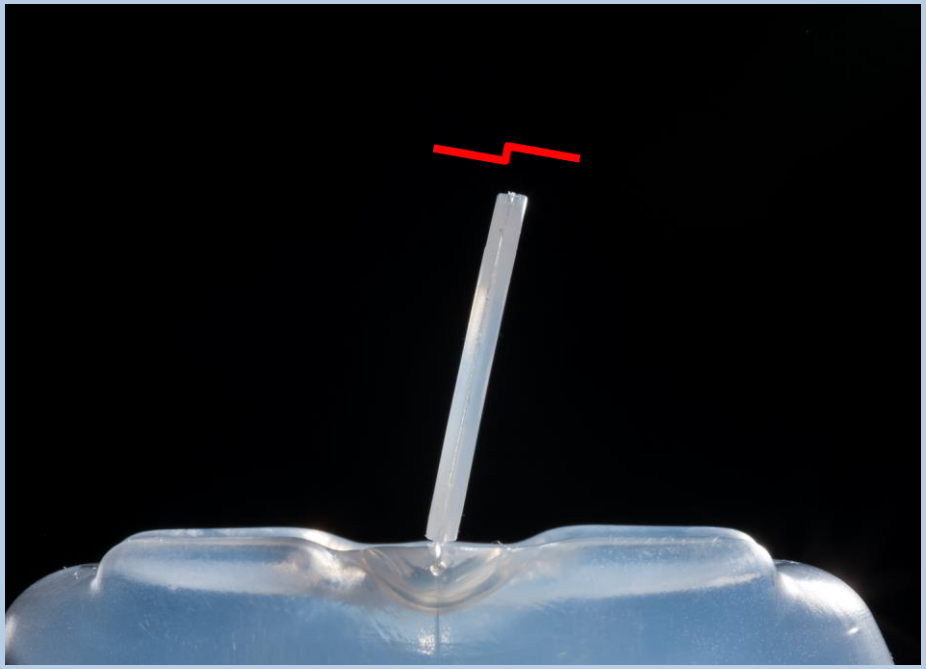
RE-0133	Description	Picture
Defect designation	Dent	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Shoulder	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0037	Description	Picture
Defect designation	General Deformation	 
Defect occurrence (process)	Punch	
Defect Position (Container)	Twist Off	
Defect Type	Deformation (moulding)	
Criticality	Minor/Major if defined breaking point is affected	

RE-0029	Description	Picture
Defect designation	General Deformation	 
Defect occurrence (process)	Deflashing	
Defect Position (Container)	Head	
Defect Type	Deformation (moulding)	
Criticality	Minor	

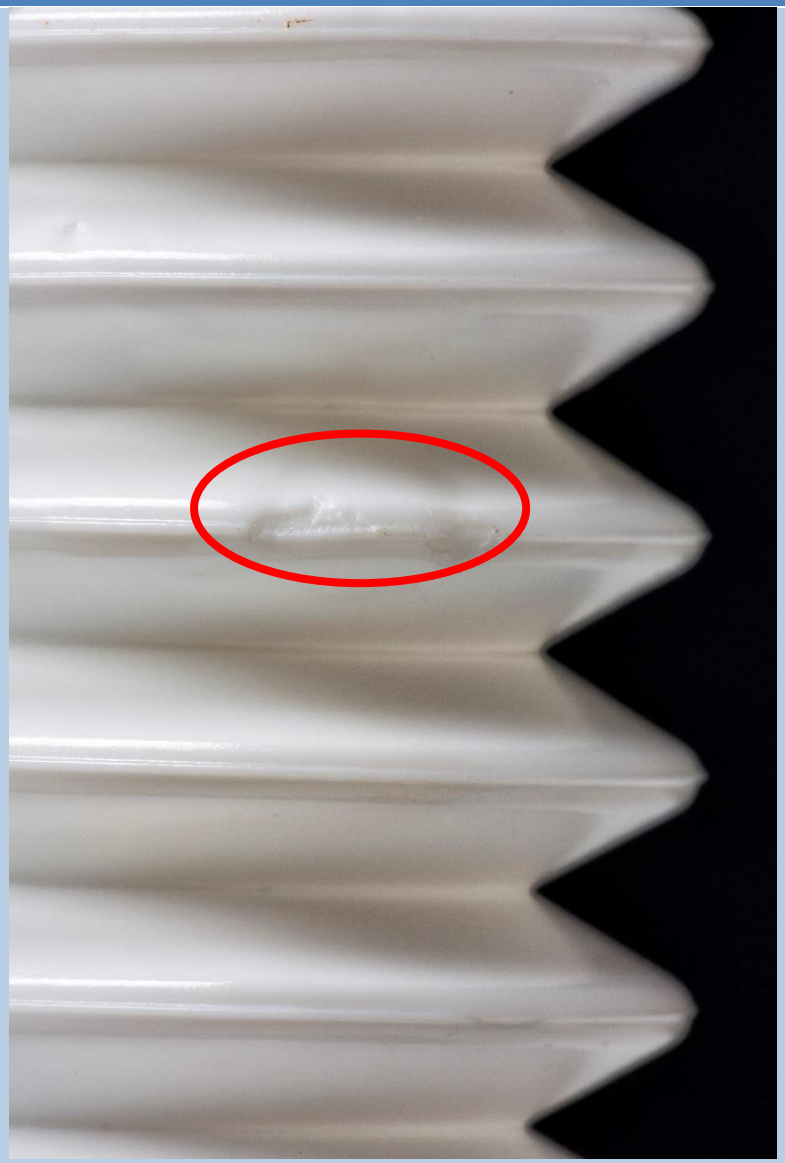
RE-0221	Description	Picture
Defect designation	General Deformation	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Shoulder	
Defect Type	Deformation (Moulding)	
Criticality	Minor	

RE-0225	Description	Picture
Defect designation	Function Defect	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Head	
Defect Type	Deformation (Moulding)	
Criticality	Major	

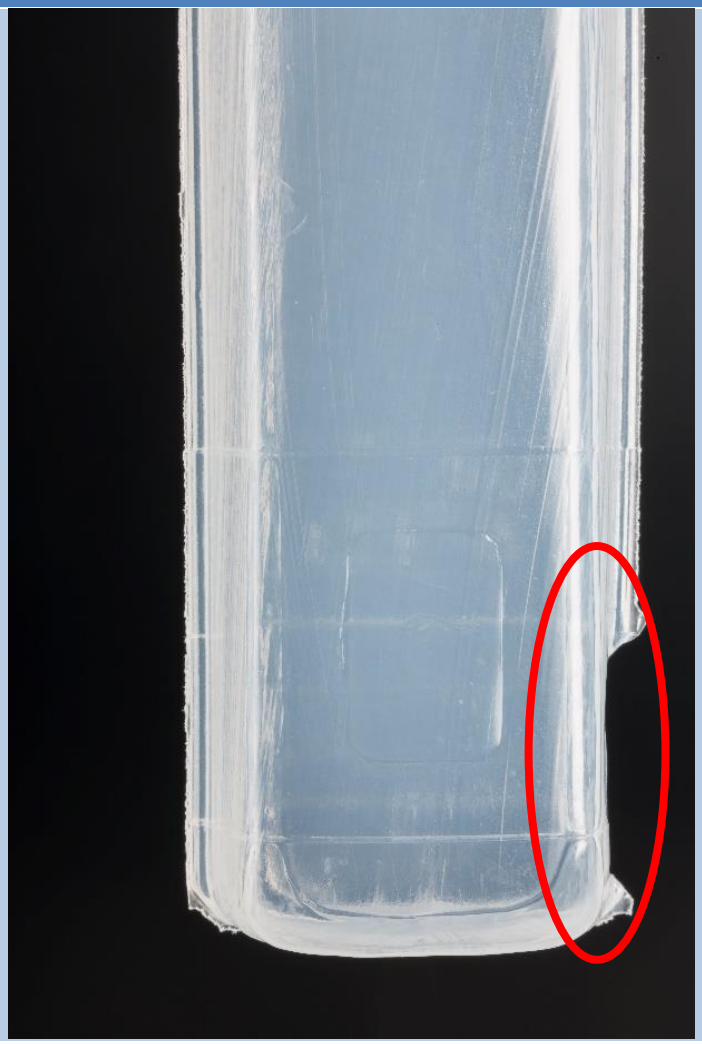
RE-0272	Description	Picture
Defect designation	Mould Offset	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Hanger	
Defect Type	Deformation (moulding)	
Criticality	Minor	

RE-0256	Description	Picture
Defect designation	General Deformation	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body	
Defect Type	Deformation (Moulding)	
Criticality	Minor	

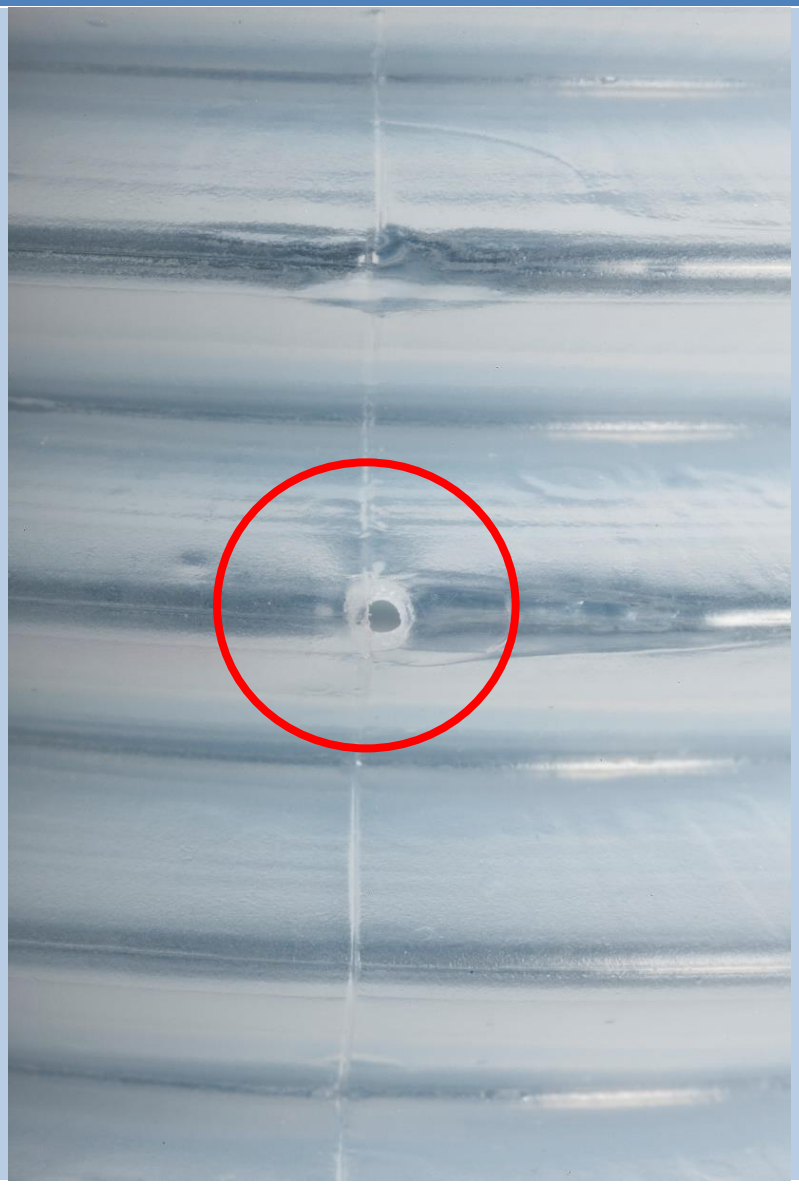
RE-0276	Description	Picture
Defect designation	General Deformation	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body	
Defect Type	Deformation (Moulding)	
Criticality	Minor	

RE-0100	Description	Picture
Defect designation	General Deformation	 
Defect occurrence (process)	Handling	
Defect Position (Container)	Body	
Defect Type	Deformation (Moulding)	
Criticality	Minor	

6.4 Lack of Material

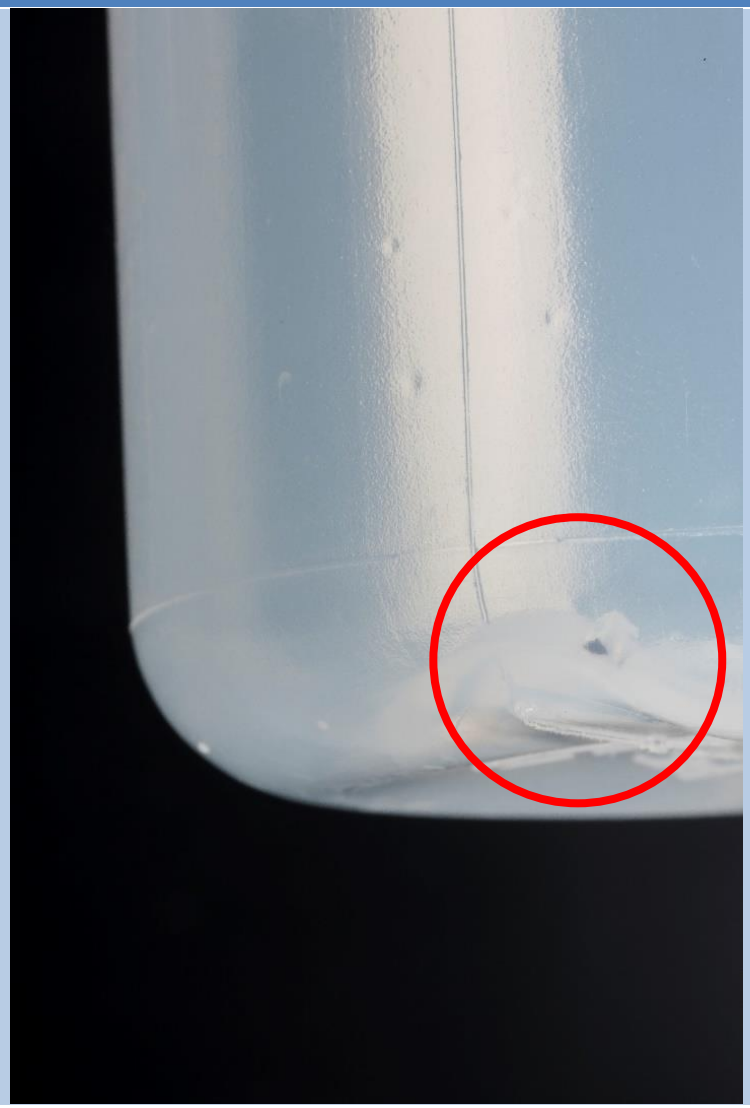
RE-0064	Description	Picture
Defect designation	Cut	 
Defect occurrence (process)	Parison Control	
Defect Position (Container)	Body	
Defect Type	Lack of Material	
Criticality	Major	

RE-0093	Description	Picture
Defect designation	Hole external	 
Defect occurrence (process)	Filling	
Defect Position (Container)	Shoulder	
Defect Type	Lack of Material	
Criticality	Critical	

RE-0069	Description	Picture
Defect designation	Hole external	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body	
Defect Type	Lack of Material	
Criticality	Critical	

RE-0235	Description	Picture
Defect designation	Thinned Area	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Bottom	
Defect Type	Lack of Material	
Criticality	Minor/Major if wall thickness is out of spec.	

6.5 Particles

RE-0089	Description	Picture
Defect designation	Free Particle	
Defect occurrence (process)	Filling	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Critical	

RE-0138	Description	Picture
Defect designation	Embedded particle	 
Defect occurrence (process)	Extrusion	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Minor/Major (Size and AQL dependent)	

RE-0102	Description	Picture
Defect designation	Embedded particle	
Defect occurrence (process)	Extrusion	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Minor/Major (Size and AQL dependent)	

RE-0068-1	Description	Picture
Defect designation	Crystallization	 
Defect occurrence (process)	Filling	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Minor (inherent)	

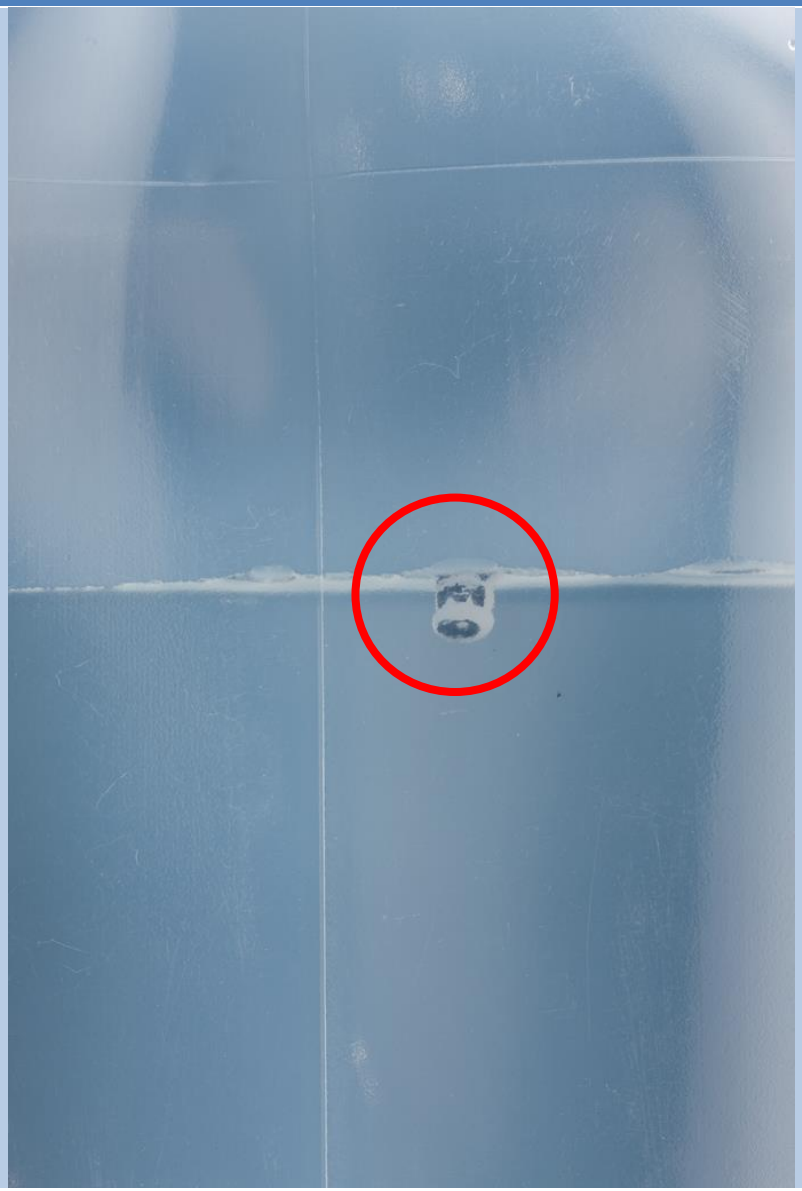
RE-0099	Description	Picture
Defect designation	Crystallization	 
Defect occurrence (process)	Filling	
Defect Position (Container)	Neck	
Defect Type	Particles	
Criticality	Minor (inherent)	

RE-0068-2	Description	Picture
Defect designation	Embedded particle	
Defect occurrence (process)	Extrusion	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Minor/Major (Size and AQL dependent)	

RE-0210	Description	Picture
Defect designation	White Spot	 
Defect occurrence (process)	Extrusion	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Minor (Paraffin intrinsic)	

RE-0223	Description	Picture
Defect designation	Free floating	
Defect occurrence (process)	Filling Mandrel	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Critical	

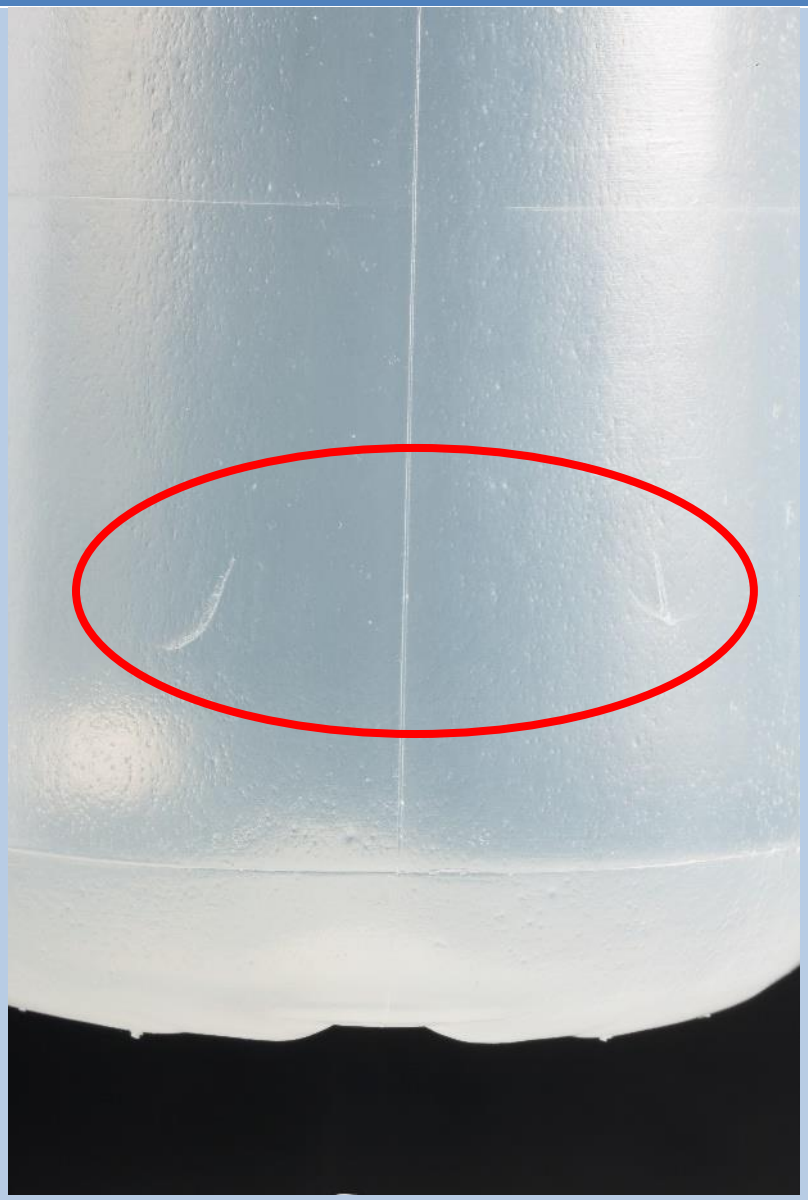
RE-0240	Description	Picture
Defect designation	Free floating	
Defect occurrence (process)	Filling Mandrel	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Critical	

RE-0231	Description	Picture
Defect designation	Free floating	
Defect occurrence (process)	Filling Mandrel	
Defect Position (Container)	Body	
Defect Type	Particles	
Criticality	Critical	

6.6 Deformation (handling)

RE-0106	Description	Picture
Defect designation	Scratches	 
Defect occurrence (process)	Handling	
Defect Position (Container)	Body	
Defect Type	Deformation (handling)	
Criticality	Minor	

RE-0104	Description	Picture
Defect designation	Scratches	 
Defect occurrence (process)	Handling	
Defect Position (Container)	Body	
Defect Type	Deformation (handling)	
Criticality	Minor	

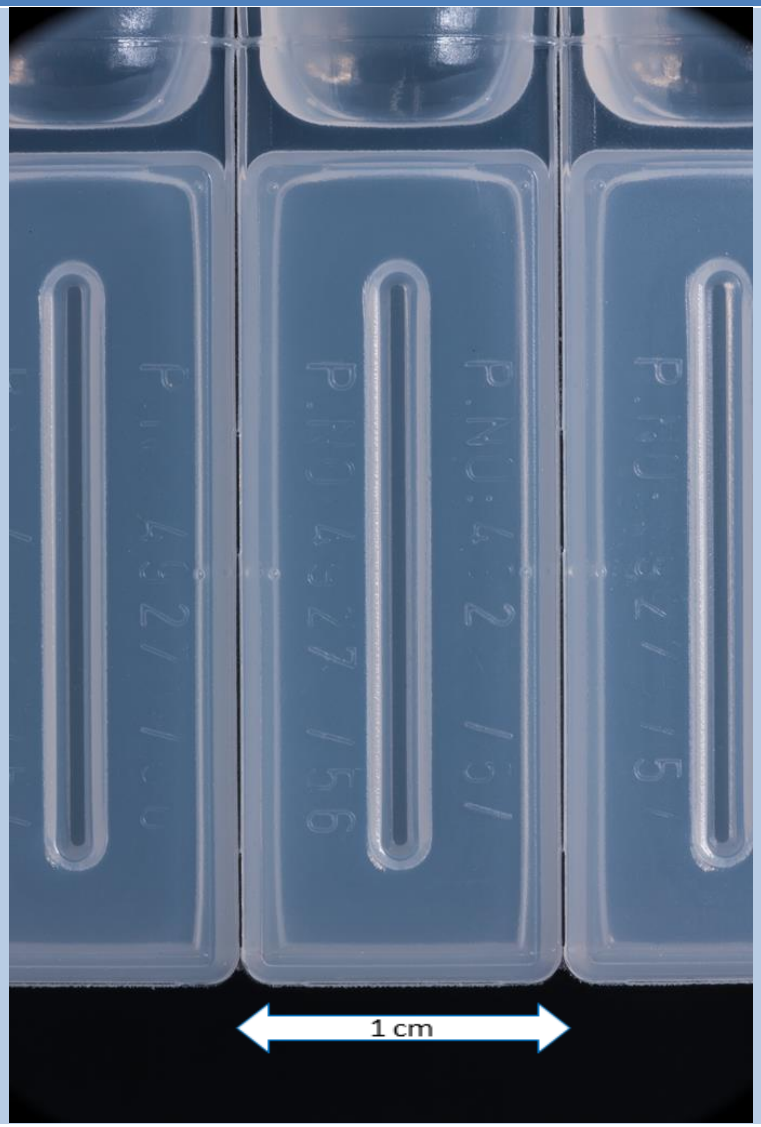
RE-0041	Description	Picture
Defect designation	Scratches	 
Defect occurrence (process)	Handling	
Defect Position (Container)	Body	
Defect Type	Deformation (handling)	
Criticality	Minor	

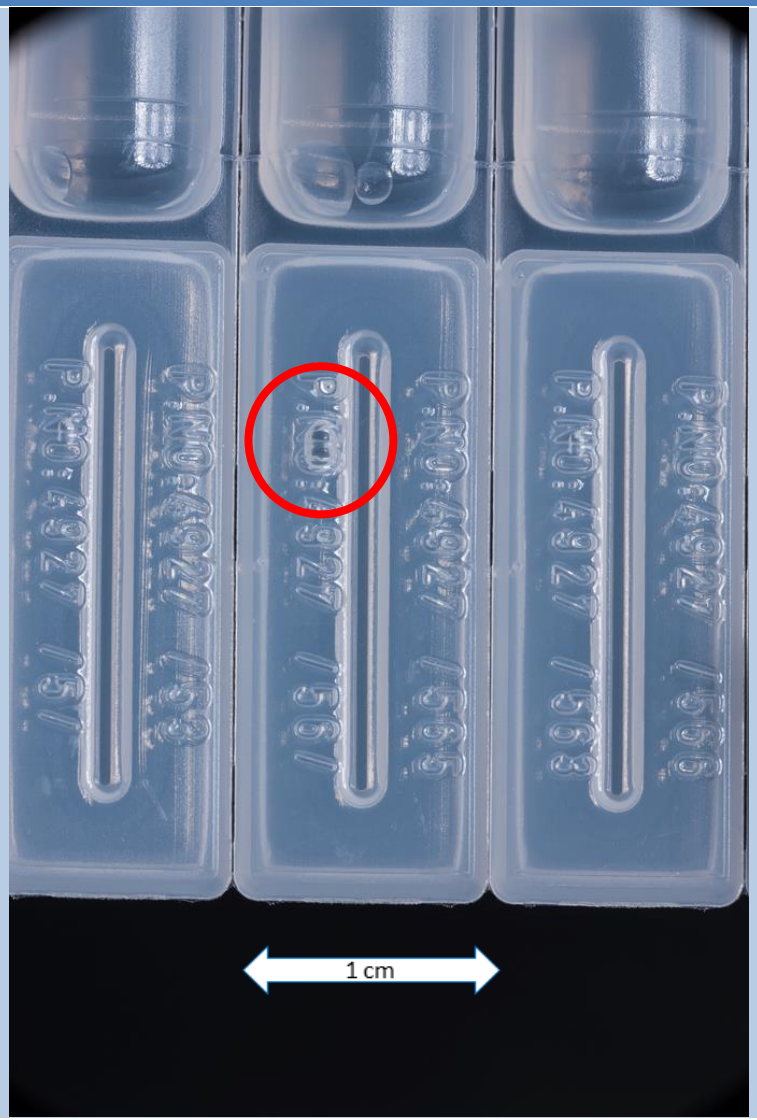
RE-0277	Description	Picture
Defect designation	Scratches	 
Defect occurrence (process)	Handling Grippers	
Defect Position (Container)	Body	
Defect Type	Deformation (handling)	
Criticality	Minor	

RE-0189	Description	Picture
Defect designation	Mechanical Deformation	 
Defect occurrence (process)	Punch	
Defect Position (Container)	Head	
Defect Type	Deformation (handling)	
Criticality	Major/Critical if CCI is affected	

6.7 Engraving

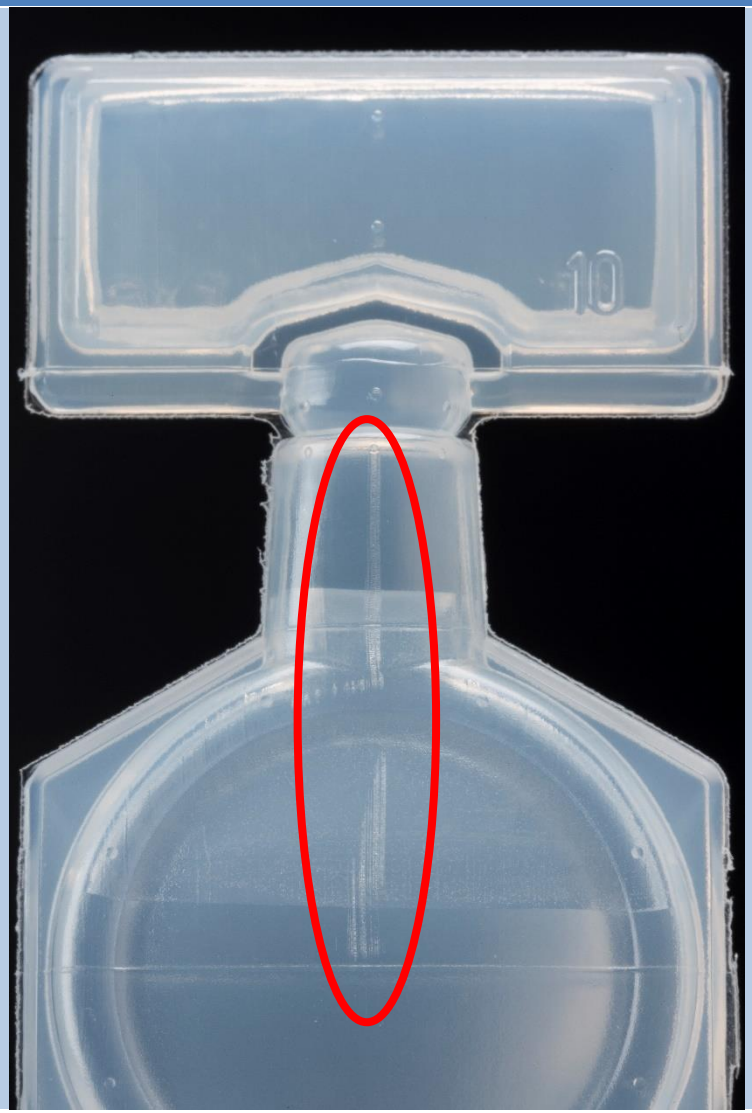
RE-0065	Description	Picture
Defect designation	Illegibility	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body	
Defect Type	Engraving	
Criticality	Critical	

RE-0212	Description	Picture
Defect designation	Illegibility	
Defect occurrence (process)	Hot Stamp	
Defect Position (Container)	Flag	
Defect Type	Engraving	
Criticality	Major/Critical if illegible	

RE-0217	Description	Picture
Defect designation	Illegibility	
Defect occurrence (process)	Hot Stamp	
Defect Position (Container)	Flag	
Defect Type	Engraving	
Criticality	Major/Critical if illegible	

6.8 Other

RE-0226	Description	Picture
Defect designation	Puncture	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body	
Defect Type	Other	
Criticality	Critical	

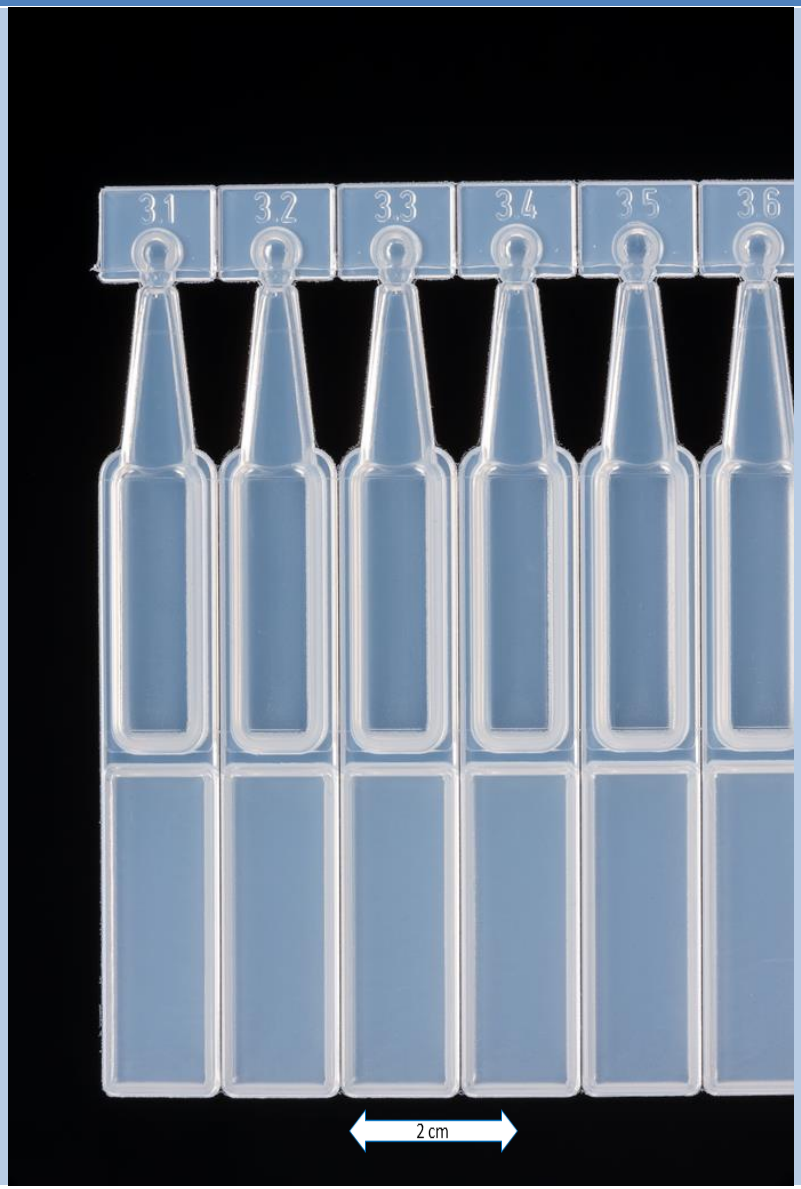
RE-0088	Description	Picture
Defect designation	Scratches	 
Defect occurrence (process)	Handling	
Defect Position (Container)	Body	
Defect Type	Other	
Criticality	Minor	

RE-0105	Description	Picture
Defect designation	Inflated	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Flag	
Defect Type	Others	
Criticality	Minor	

RE-0229	Description	Picture
Defect designation	Vacuum	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Head	
Defect Type	Other	
Criticality	Minor	

RE-0236	Description	Picture
Defect designation	Leaking (internal)	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Twist off	
Defect Type	Other	
Criticality	Major	

RE-0239	Description	Picture
Defect designation	Mechanical Deformation	 
Defect occurrence (process)	Punch	
Defect Position (Container)	Twist off	
Defect Type	Other	
Criticality	Minor/Critical if CCI is affected	

RE-0239	Description	Picture
Defect designation	Mechanical Deformation	 
Defect occurrence (process)	Punch	
Defect Position (Container)	Neck	
Defect Type	Other	
Criticality	Minor	

RE-0262	Description	Picture
Defect designation	Trapped Air/Mechanical Deformation	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Twist Off	
Defect Type	Other	
Criticality	Minor (position not critical) Critical if CCI is affected	

RE-0266	Description	Picture
Defect designation	Mechanical Deformation	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Neck	
Defect Type	Other	
Criticality	Minor	

RE-0268	Description	Picture
Defect designation	Mechanical Deformation	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Neck	
Defect Type	Other	
Criticality	Minor	

RE-0241	Description	Picture
Defect designation	Extrusion	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body	
Defect Type	Other	
Criticality	Minor	

RE-0075	Descritption	Picture
Defect designation	Mechanical Deformation	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Neck	
Defect Type	Other	
Criticality	Minor	

RE-0200	Description	Picture
Defect designation	Mechanical Deformation	 
Defect occurrence (process)	Deflashing	
Defect Position (Container)	Head	
Defect Type	Other	
Criticality	Minor	

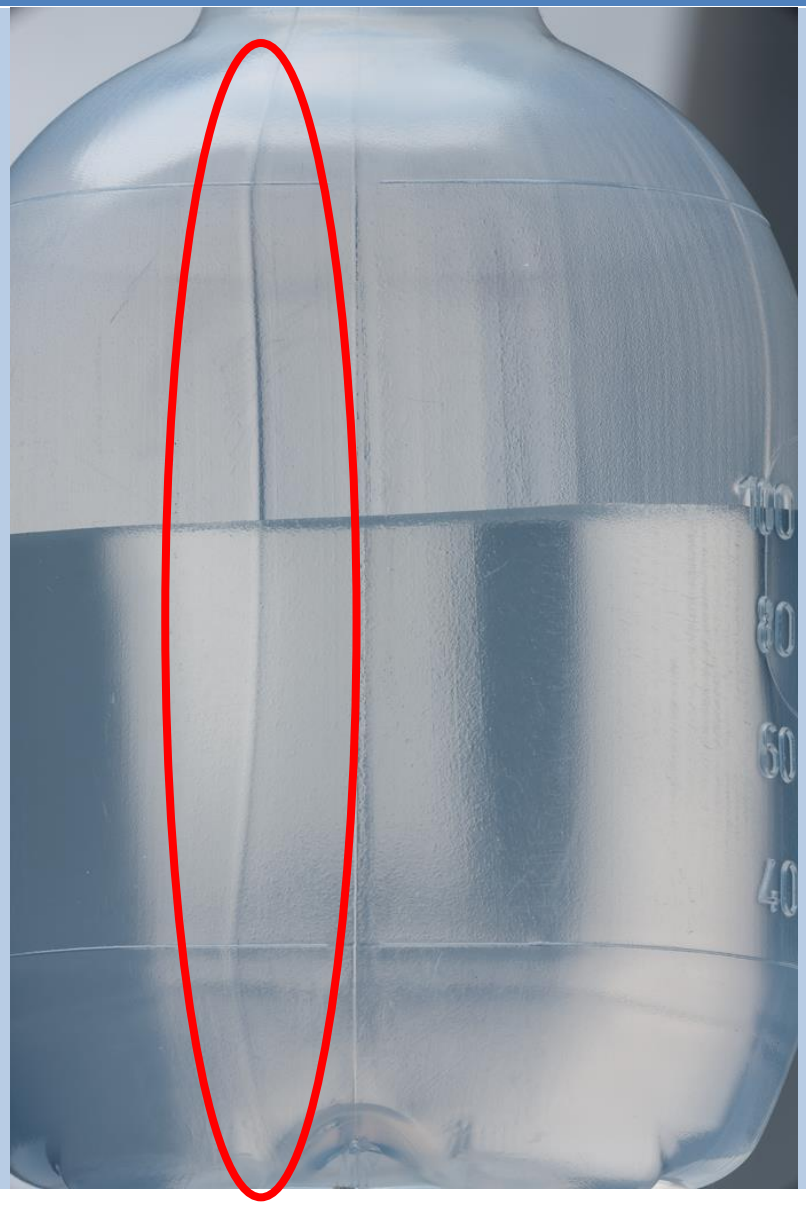
RE-0219	Description	Picture
Defect designation	Excess Material	 
Defect occurrence (process)	Deflashing	
Defect Position (Container)	Head	
Defect Type	Other	
Criticality	Major (Cap welding process affected) Critical if CCI is affected	

RE-0222	Description	Picture
Defect designation	Mechanical Deformation	
Defect occurrence (process)	Deflashing	
Defect Position (Container)	Body	
Defect Type	Other	
Criticality	Minor	

RE-0205	Description	Picture
Defect designation	Mechanical Deformation	
Defect occurrence (process)	Filling	
Defect Position (Container)	Head	
Defect Type	Other	
Criticality	Minor	

RE-0273	Description	Picture
Defect designation	Scratches	
Defect occurrence (process)	Deflashing	
Defect Position (Container)	Body	
Defect Type	Other	
Criticality	Minor	

RE-0274	Description	Picture
Defect designation	Mechanical Deformation	
Defect occurrence (process)	Filling	
Defect Position (Container)	Neck	
Defect Type	Other	
Criticality	Minor	

RE-0276	Description	Picture
Defect designation	Mechanical Deformation	 
Defect occurrence (process)	Extrusion	
Defect Position (Container)	Body	
Defect Type	Other	
Criticality	Minor	

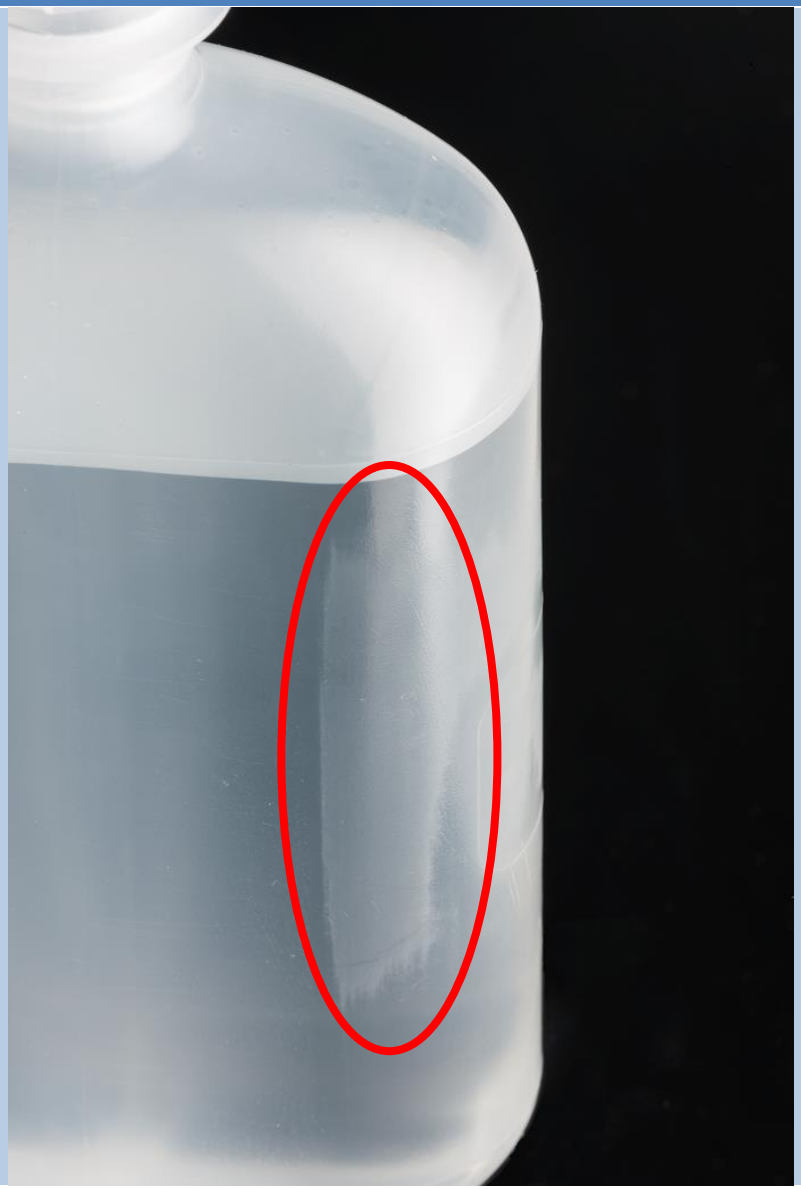
RE-0232	Description	Picture
Defect designation	Mechanical Deformation	
Defect occurrence (process)	Moulding	
Defect Position (Container)	Head	
Defect Type	Other	
Criticality	Minor/Major if CCI or welding are affected	

RE-0233	Description	Picture
Defect designation	Mechanical Deformation	
Defect occurrence (process)	Moulding Alignment	
Defect Position (Container)	Head	
Defect Type	Other	
Criticality	Minor	

RE-0233	Description	Picture
Defect designation	Mechanical Deformation	 
Defect occurrence (process)	Deflashing	
Defect Position (Container)	Head	
Defect Type	Other	
Criticality	Minor	

RE-0251	Description	Picture
Defect designation	Trapped Air	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Head	
Defect Type	Other	
Criticality	Critical because CCI is affected	

RE-0284	Description	Picture
Defect designation	Transparency	
Defect occurrence (process)	Extrusion	
Defect Position (Container)	Body	
Defect Type	Other	
Criticality	Minor	

RE-0286	Description	Picture
Defect designation	Transparency/ Optical Appearance	 
Defect occurrence (process)	Moulding	
Defect Position (Container)	Body	
Defect Type	Other	
Criticality	Minor	

7 Bibliography

European Comission. (2020, Dec.). Retrieved from Revision of Annex 1, on manufacturing of sterile medicinal products, of Eudralex volume 4: https://ec.europa.eu/health/sites/health/files/files/gmp/2020_annex1ps_sterile_medicinal_products_en.pdf

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