3.2.P.3.4. IN-PROCESS MONITORING AND CONTROL – FILL AND FINISH –- PRE-FILLED SYRINGE (REFRIGERATED, GLASS) [PUURS]

This section provides the relevant process parameters and in-process tests for control (IPT-C), with their acceptable ranges/acceptance criteria, for the fill and finish manufacturing operations in Pfizer Puurs.

3.2.P.3.4.1. Sterile Filtration

Sterile filtration process controls and acceptable range/acceptance criteria are provided in Table 3.2.P.3.4-1. Microbial process control and acceptance criterion are provided in Table 3.2.P.3.4-2.

Table 3.2.P.3.4-1. Process Controls for Sterile Filtration

Process Control	Category	Acceptance Criteria			
		4.2 1st ind	Filter	4.2 1st ind	Filter
4.2 1st ind	4.2 1st ind				
4.2 1st ind					

Table 3.2.P.3.4-2. Microbial Process Control for Sterile Filtration

Process Control	Category	Acceptance Criterion
4.2 1st ind		
4.2 1st ind		

The filter integrity testing is performed 4.2 1st ind Different control limits can be applied for both pre-use and post-use filter integrity testing, depending on the wetting agent and temperature, as detailed in Table 3.2.P.3.4-3 and Table 3.2.P.3.4-4. A successful filter integrity test meeting any one of these control limits will be considered a successful filter integrity test.

Table 3.2.P.3.4-3. Control Limits for Filter Integrity Testing - 4.2 1st ind

Wetting Agent	Control Limit
4.2 1st ind	

Table 3.2.P.3.4-4. Control Limits for Filter Integrity Testing – 4.2 1st ind

Wetting Agent	Control Limit
4.2 1st ind	

3.2.P.3.4.2. Aseptic Filling and Plunger Placement

The fill weight and plunger placement target for aseptic syringe filling is detailed in Table 3.2.P.3.4-5 and the IPT-C for the fill weight and plunger placement is detailed in Table 3.2.P.3.4-6.

Table 3.2.P.3.4-5. Process Parameters for Aseptic Filling – PFS (Refrigerated, Glass)

Process Parameter	Category	Target
4.2 1st ind		
4.2 1st ind		

Table 3.2.P.3.4-6. IPT-C Test for Aseptic Filling – PFS (Refrigerated, Glass)

In-process Test	Category	Acceptance Criterion
4.2 1st ind		
4.2 1st ind		

During production, in-process fill weight and plunger placement tests are performed at routine intervals. 4.2 1st ind

An additional process control for aseptic filling is detailed in Table 3.2.P.3.4-7.

Table 3.2.P.3.4-7. Additional Process Control for Aseptic Filling - PFS (Refrigerated, Glass)

Filling line	Process Control	Category	Acceptable Range
4.2 1st ind			
4.2 1st ind			

3.2.P.3.4.3. Storage

PFS (Refrigerated, Glass) is stored according to conditions supported by the stability data detailed in Section 3.2.P.8.1 Stability Summary and Conclusions – Bivalent [Original and Omicron (BA.4-BA.5)] – PFS (Refrigerated, Glass) and Section 3.2.P.8.1 Stability Summary and Conclusions – [Omicron (XBB1.5)] – PFS (Refrigerated, Glass).