FilterPES 0.2 micron

VALIDATION GUIDE

IPM
SISTEMI DI FILTRAZIONE

➤ Summary

Contents

➤General information about filter cartridges FilterPES

In a pharmaceutical production process, filtration is a very important step. It guarantees the depletion of any particles or microbial contaminants from the drug being processed. The filtration process must meet high and well defined quality standards.
Filter cartridges validation is mandatory to ensure purity, security and effectiveness to a pharmaceutical product.
The purpose of this document is to supply with useful information every End User of FilterPES filter cartridges.0.2 µ m rated, operating i n ph armaceutical app lications. T he doc ument provides al l references abou t t est m ethods us ed a nd r esults ob tained c onfirming c artridges c onformity to t he applicable requirements.
FilterPES filter cartridges 0.2 micron rated, are designed and manufactured for use in production of sterile liquids in pharmaceutical industry. Materials used for the assembly of the cartridges, both the Polytetrafluoroethylene(PTFE) membrane and the Polypropylene polymer used for the hardware supports, had been selected for the specific application meeting the current regulations.
All t he assembling steps ar e carried out b y m eans of thermal bondi ng pr ocesses, w ithout ad ding adhesive m aterial.. *FilterPES* filter c artridges 0. 2 micron r ated, are c onstructed i n c ontrolled contamination clean room and tested prior to the shipment by QA & QC IPM labs, following internal procedures, in order to meet the reference values set.
The identification of the *FilterPES* filter cartridges is made per the following schema:

PES	D	10	002	S	I	PH
Product identification **PES**	Cartridge ty pe	Lenght	Filtration Rating	Gaskets O-rings	Insert	Version
	D = DOE (Double Open End) **2** = bayonet 2 226/flat **3** = 2 222/flat **5** = 3 bayonet 2 222/tip **7** = bayonet 226/tip **8** = 2 222/tip	10=10" 20=20" 30=30" 40=40"	002= 0,2 µm 004 = 0,45 µm 006 = 0,65 µm 008 = 0,8 µm 012 = 1,2 µm	B = Buna N E = EPDM S = Silicone V = Viton X = other* * Contact IPM	I = with SS insert (*) 0 = W/o SS insert (*) When filter has to be sterilised by steam	PH= Pharma Version
	J = JUNIOR cartridge	02=2.5" 05=5"				

Should you need more info, please contact IPM technical support tel. +39 039 21 45 244 or visit the site www.ipmfilters.com

➤Filter cartridges FilterPES 0,2 µm-technical characteristics

<table>
<tr><td colspan="5">Materials of construction</td></tr>
<tr><td>Membrane</td><td colspan="4">Polietersulfone (PES)</td></tr>
<tr><td>Support layers</td><td colspan="4">Polypropylene (PP)</td></tr>
<tr><td>Cartridge supports</td><td colspan="4">Polypropylene (PP)</td></tr>
<tr><td>O-rings</td><td colspan="4">Silicone</td></tr>
<tr><td colspan="5">Technical characteristics</td></tr>
<tr><td>Filtration area</td><td colspan="4">0.78 m^2 (10'' module)</td></tr>
<tr><td>Pores size</td><td colspan="4">0.2 µm</td></tr>
<tr><td>Length</td><td colspan="4">Cartridges are available with the following dimensions:
5'' JUNIOR (125 mm), 10'' (250 mm), 20'' (500 mm), 30'' (750 mm)</td></tr>
<tr><td colspan="5">Retention characteristics</td></tr>
<tr><td>Bacterial retention</td><td colspan="4">Retention of 10^7 CFU/cm^2 Brevundimonas diminuta (ATCC 19146), as per ASTM F838-05.</td></tr>
<tr><td colspan="5">Mechanical characteristics</td></tr>
<tr><td rowspan="4">Hydraulic Stress Resistance</td><td colspan="4">FilterPES filter cartridges 0,2 µm rated showed to retain their diffusion and integrity characteristics after the following hydraulic stress tests</td></tr>
<tr><td>Water Pressure (bar)</td><td>N° of strokes</td><td>Water temperature (°C)</td><td>Flow direction</td></tr>
<tr><td>5.0</td><td>50</td><td>20±5</td><td>Forward</td></tr>
<tr><td>2.0</td><td>50</td><td>20±5</td><td>Reverse</td></tr>
<tr><td rowspan="3">Thermal Stress Resistance</td><td colspan="4">FilterPES filter cartridges 0,2 µm rated showed to retain their diffusion and integrity characteristics after the following thermal stress tests</td></tr>
<tr><td>Temperature Test (°C)</td><td>Pressure Test (bar)</td><td>Cycle Time[1] (hours)</td><td>N° of cycles (in autoclave)</td></tr>
<tr><td>121</td><td>1.15</td><td>1</td><td>50</td></tr>
<tr><td colspan="5">Estractables</td></tr>
<tr><td>Estractables</td><td colspan="4">FilterPES 0.2 filter cartridges meet USP<661>.</td></tr>
<tr><td>Conformity of materials to the rules for food contact</td><td colspan="4">The materials used to produce the FilterPES 0,2 µm cartridge filters were confirmed to be compliant with the requirements for food contact prescribed in Reg. N° 1935/2004/EEC and meet the FDA Indirect Food Additive requirements cited in 21 CFR 177 – 182.</td></tr>
<tr><td colspan="5">Biological reactivity</td></tr>
<tr><td>Toxicity of materials</td><td colspan="4">All the materials of the FilterPES 0,2 µm filter cartridges meet the requirements of USP<87> ("Biological Reactivity Test in vitro for Class VI Plastics") and USP<88> ("Biological Reactivity Test in vivo for Class VI Plastics – Safety Test").</td></tr>
<tr><td colspan="5">Release of particles and/or Endotoxins</td></tr>
<tr><td>Bacterial endotoxins</td><td colspan="4">< 0.125 EU/mL of aqueous extract as per USP<85>.</td></tr>
<tr><td>Non-fibre releasing</td><td colspan="4">FilterPES 0.2 µm filter cartridges satisfy the requirements as per USP<788></td></tr>
</table>

[1] Total time considering warming up time of 15 minutes; 30 minutes at test temperature and 15 minutes for cooling down to ambient temperature.

➤Bacteria removal efficiency

Regulator Authorities FDA and EMA, set the rule to demonstrate the sterilizing action of a filter before to start to use it in pharmaceutical applications. So, the sterilizing grade of a filter cannot be set only by the rating of pores dimension.
In order to consider a filter of sterilizing grade it must be submitted to a process simulation challenging it by a bacterial suspension of Brevundimonas diminuta ATCC 1946 at the concentration of not less than 107 CFU/cm2. The downstream fluid must be sterile.
The correlation between the microbial retention and the non-destructive integrity test is another very important aspect of the validation of a pharmaceutical grade filter cartridge.
The Regulator Authorities require a procedure to control the filter both prior and after the use.
Hereinafter are reported the Challenge tests results of tests made on FilterPES filter cartridges 0.2 µm rated. According to the ASTM F838-05 methodology, the tests demonstrate the ability of membranes, used to produce FilterPES, to fully retain a Brevundimonas diminuta bacterial charge of 107 CFU/cm2.
You can also find the correlation between the retention and the diffusion test.
This correlation is important to set the maximum diffusion flow acceptance limit to guarantee that the filter will produce a sterile effluent.
In the following tables are reported the correlation between the diffusion test (non destructive test) and the bacterial challenge test (destructive test) for FilterPES 0.2 µm filter cartridges Part Number: PES J05 002 SI - PH ; PES 710 002 SI - PH and PES 7 20 002 SI - PH.

➤Filter Cartridge type PES J05 002 S I - PH 0,2 micron rated Challenge test

To perform the test, 20 filter cartridges were withdrawn from normal production. Each cartridge has been tested by diffusion test and then challenged by a suspension of Brevundimonas diminuta at the concentration > 10^7 CFU/cm^2. Numerical and graphical results are reported in Table 1 and Figure 1 respectively. The filter cartridges PES J05 002 S I – PH meet acceptability criteria on performance basis..

LOT N°	DIFFUSION AT 2200 mbar mL/min	DOWNSTREAM STERILITY	TITLE REDUCTION
6060/34	7,0	Si	> 1,4 x 10^8
5953/45	7,5	Si	> 1,5 x 10^8
5750/28	7,7	Si	> 1,9 x 10^8
5606/27	7,5	Si	> 1,3 x 10^8
5750/26	7,2	Si	> 1,7 x 10^8
5953/15	7,5	Si	> 1,4 x 10^8
5750/39	7,5	Si	> 1,8 x 10^8
5750/04	8,0	Si	> 1,4 x 10^8
5953/22	8,3	Si	> 1,9 x 10^8
5606/50	8,5	Si	> 1,3 x 10^8
5750/36	8,5	Si	> 1,6 x 10^8
5750/10	8,0	Si	> 1,3 x 10^8
5750/32	8,2	Si	> 1,2 x 10^8
5606/25	8,6	Si	> 1,3 x 10^8
5750/37	8,8	Si	> 1,5 x 10^8
5953/34	9,0	Si	> 1,8 x 10^8
5606/02	9,5	Si	> 1,7 x 10^8
5606/51	12,0	Si	> 1,1 x 10^9
5953/13	12,5	No	1,1 x 10^6
5953/23	14,0	No	1,9 x 10^6
5750/30	14,5	Si	> 1,9 x 10^8

Table 1- FilterPES: PES J05 002 S I - PH filter cartridges 0.2 µm rated
Results of bacterial retention test

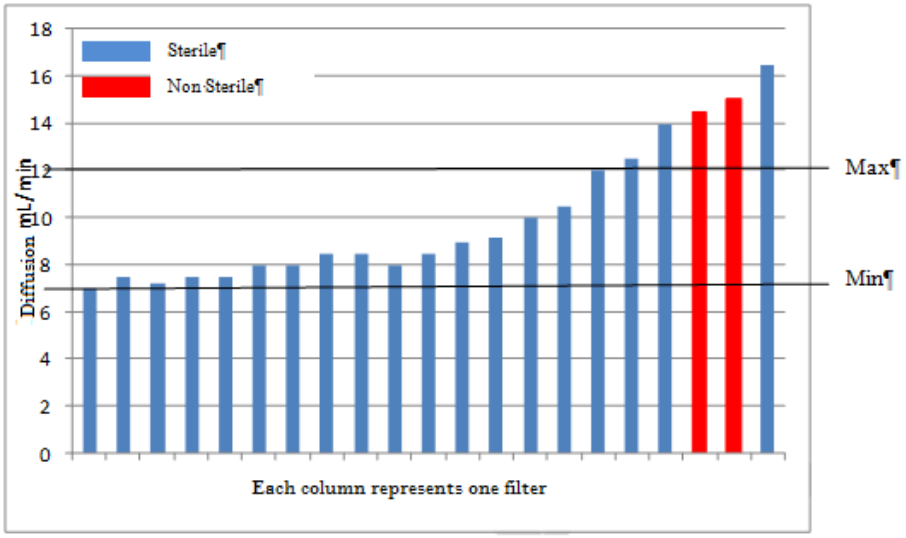


Figure 1- FilterPES: PES J05 002 S I - PH filter cartridges 0.2 µm rated. Correlation between diffusion and bacterial retention test. ASTM F838-05

On performance basis, FilterPES filter cartridges PES J05 002 SI - PH 0.2 micron rated meet acceptability criteria and are considered to be a sterilizing filters within a maximum diffusion value of 12,0 mL/min.

➤Filter cartridge type PES 7 10 002 S I – PH correlation diffusion vs retention

To perform the test, 20 filter cartridges were withdrawn from normal production. Each cartridge has been tested by diffusion test and then challenged by a suspension of Brevundimonas diminuta at the concentration > 10^7 CFU/cm^2. Numerical and graphical results are reported in Table 2 and Figure 2 respectively. The filter cartridges PES 7 10 002 S I – PH meet acceptability criteria on performance basis.

LOT N°	DIFFUSION AT 2200 mbar ml/min	DOWNSTREAM STERILITY	TITLE REDUCTION
6733/34	14,5	Si	> 1,2 x 10^8
6945/45	14,7	Si	> 1,7 x 10^8
7045/28	15,0	Si	> 1,3 x 10^8
6733/27	15,0	Si	> 1,5 x 10^8
7045/26	15,5	Si	> 1,4 x 10^8
6945/15	15,5	Si	> 1,2 x 10^8
7045/39	16,0	Si	> 1,6 x 10^8
7045/04	16,0	Si	> 1,2 x 10^8
6945/22	16,0	Si	> 1,7 x 10^8
6733/50	16,5	Si	> 1,1 x 10^8
7045/36	16,5	Si	> 1,8 x 10^8
7045/10	17,0	Si	> 1,6 x 10^8
7045/32	17,0	Si	> 1,1 x 10^8
6733/25	17,5	Si	> 1,4 x 10^8
7045/37	17,5	Si	> 1,2 x 10^8
6945/34	17,5	Si	> 1,8 x 10^8
6733/02	18,0	Si	> 1,6 x 10^8
6733/51	19,5	Si	> 1,1 x 10^9
6945/13	20,5	No	1,6 x 10^6
6945/23	23,0	No	1,4 x 10^6
7045/30	24,5	Si	> 1,6 x 10^8

Table 2- Filter PES: PES J05 002 S I - PH filter cartridges 0.2 µm
Results of bacterial retention test

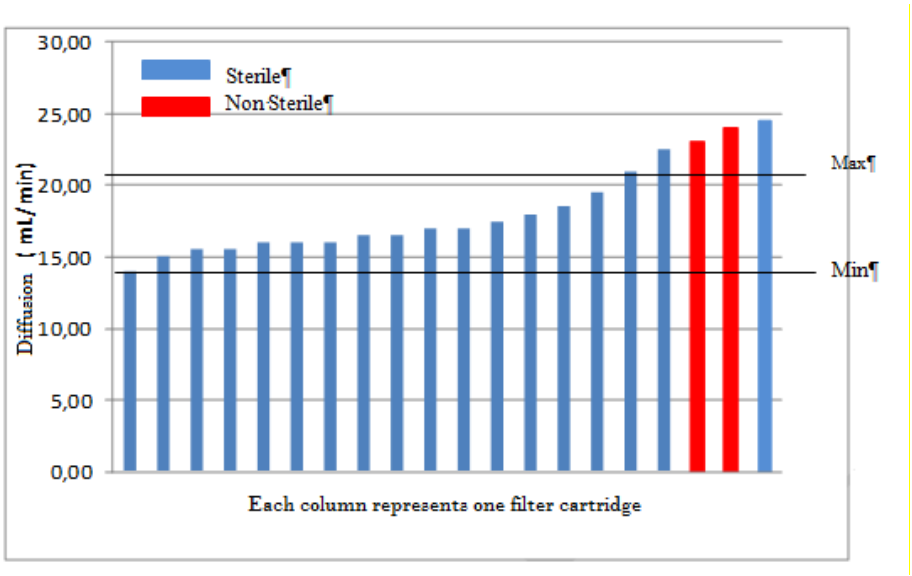


Figure 2- FilterPES: PES 7 10 002 S I - PH filter cartridges 0.2 µm rated. Correlation between diffusion and bacterial retention test. ASTM F838-05

On performance basis, FilterPES filter cartridges PES 7 10 002 S I - PH 0.2 micron rated meet acceptability criteria and are considered to be a sterilizing filters within a maximum diffusion value of 22.5 mL/min.

➤ Filter cartridge type PES 7 20 002 S I – PH correlation diffusion vs retention

To perform the test, 20 filter cartridges were withdrawn from normal production. Each cartridge has been tested by diffusion test; and then challenged by a suspension of Brevundimonas diminuta at the concentration > 10^7 CFU/cm^2. Numerical and graphical results are reported in Table 3 and Figure 3 respectively. The filter cartridges PES 7 20 002 S I – PH meet acceptability criteria on performance basis.

LOT N°	DIFFUSION AT 2200 mbar mL/min	DOWNSTREAM STERILITY	TITLE REDUCTION
4731/34	28,00	Si	> 1,8 x 10^8
4253/45	28,50	Si	> 1,4 x 10^8
5277/28	28,50	Si	> 1,9 x 10^8
5906/27	29,00	Si	> 1,3 x 10^8
5277/26	29,50	Si	> 1,6 x 10^8
4953/15	30,00	Si	> 1,3 x 10^8
5277/39	30,20	Si	> 1,4 x 10^8
5277/04	30,50	Si	> 1,5 x 10^8
5953/22	30,50	Si	> 1,9 x 10^8
5906/50	31,00	Si	> 1,3 x 10^8
5277/36	31,50	Si	> 1,7 x 10^8
5277/10	32,00	Si	> 1,4 x 10^8
5277/32	32,50	Si	> 1,2 x 10^8
5906/25	33,00	Si	> 1,3 x 10^8
5277/37	33,50	Si	> 1,5 x 10^8
5233/34	34,00	Si	> 1,8 x 10^8
5956/02	35,00	Si	> 1,7 x 10^8
5956/51	36,00	Si	> 1,1 x 10^9
5953/13	37,50	No	1,9 x 10^6
5963/23	38,00	No	1,7 x 10^4
5277/30	38,50	Si	> 1,9 x 10^8

Table 3- Filter cartridges FilterPES: PES 7 20 002 S I – PH, 0.2 µm rated Bacterial retention test results

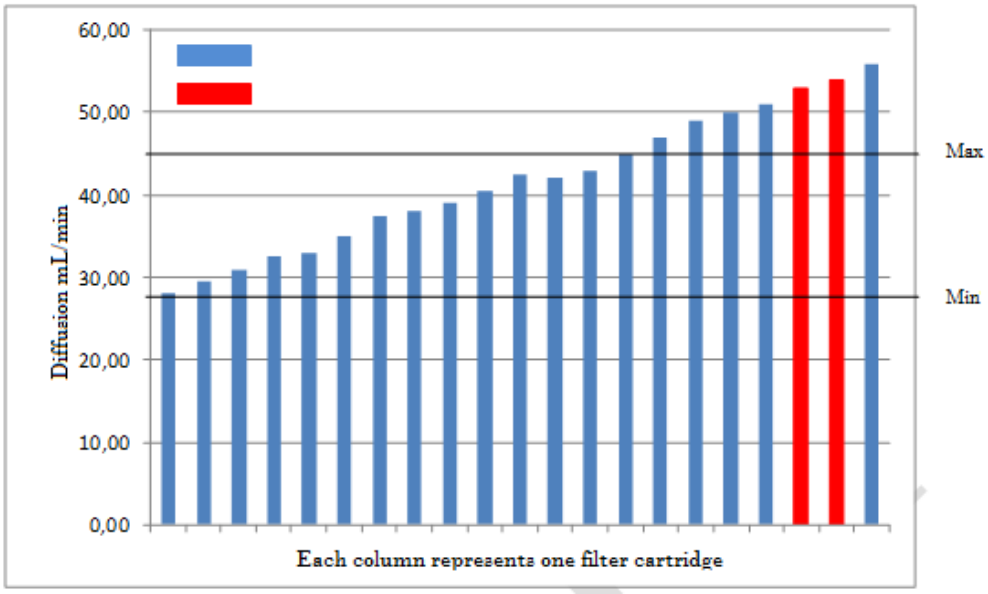


Figure 3- FilterPES filter cartridges PES 7 20 002 S I – PH 0.2 micron rated. Correlation between diffusion and microbial retention test as per ASTM F838-05

On performance basis, FilterPES filter cartridges PES 7 20 002 S I - PH 0.2 micron rated meet acceptability criteria and are considered to be a sterilizing filters within a maximum diffusion value of 45.0 mL/min.

Biological and extractables tests

➤Bacterial endotoxins – current USP <85>

The test was used to measure bacterial endotoxins released from FilterPES filter cartridge 0.2 micron rated. The test was carried out according to the Current USP<85> using the Chromogenic Method to measure the amount of endotoxins released by a filter cartridge type FilterPES 0,2 micron.
The sample cartridge was filled with a pyrogen-free water and then treated by an ultrasonic device in order to enhance endotoxins extraction.
Water samples obtained was then submitted to the analysis.
The lab test shows bacterial endotoxins level released by the filter cartridge FilterPES.
The test results demonstrate the absence of endotoxins release from FilterPES cartridges.

LOT N°	METHOD	RESULTS
5953/15	USP current version<85>	<0.25 EU/mL
6733/39	USP current version<85>	<0.25 EU/mL
5885/22	USP current version<85>	<0.25 EU/mL

Table 4-LAL test results

➤Chemical compatibility

The following table lists chemical compatibility of FilterPES filter cartridge 0.2 micron rated, when challenged with chemical products. Chemical compatibility is influenced by several parameters (temperature, concentration, contact time). IPM suggests that the Customers check chemical compatibility running a test at the same process conditions, before to use a FilterPES cartridge 0.2 micron. IPM remains available, if requested, to supply the Customer with technical support..

CHEMICAL CLASSIFICATION	COMPOUND (Test Conditions 7days at 20°C)	RESULTS
ACIDS	Acetic acid, 90%	R
	Acetic acid, 30%	R
	Acetic acid, 10%	R
	Hydrochloric acid, conc. (35%)	R
	Hydrochloric acid, 6N (20%)	R
	Hydrochloric acid, 1N (3.3%)	R
	Nitric Acid, conc. (67%)	N
	Nitric acid, 6N (27%)	R
	Sulphuric acid, conc. (96%)	N
	Sulphuric acid, 6N (16%)	-
ALCOHOLS	Amyl alcohol	N
	Benzyl alcohol	N
	Butyl alcohol	R
	Ethanol (Ethyl alcohol)	R
	Isopropanol	R
	Methanol	R
AROMATIC HYDROCARBONS	Benzene	R
	Toluene	R
	Xylene	R
BASES	Ammonium hydroxide, 3N (5.7%)	R
	Ammonium hydroxide, 6N (11.4%)	R
	Potassium hydroxide, 3N (15%)	R
	Sodium hydroxide, 3N (11%)	R
	Sodium hydroxide, 6N (22%)	R
ESTERS	Amyl acetate	R
	Butyl acetate	R
	Cellosolve acetate	R
	Ethyl acetate	N
	Isopropyl acetate	R
	Methyl acetate	N
ETHERS	Ethyl ether	R
	Tetrahydrofuran (THF)	N
	THF in water (50:50)	-
GLYCOLS	Ethylene glycol	R
	Glycerol	R
	Propylene glycol	R
HALOGENATED HYDROCARBONS	Carbon tetrachloride	R
	Chloroform	N
	Ethylene dichloride	N
	Methylene chloride	N
KETONES	Acetone	N
	Cyclohexanone	N
	Methyl ethyl ketone (MEK)	N
	Methyl isobutyl ketone	R
OILS	Cottonseed	R
	Peanut	R
MISCELLANEOUS	Acetonitrile	R
	Dimethyl-Formamide (DMF)	N
	Formaldehyde (37%)	R
	Hexane	L
	Pyridine	N

Table 5- FilterPES 0.2 micron cartridges Chemical Compatibility
(R=recommended; L=Limited resistance; N=Not Recommended; « – » Insufficient Data

➤Estractables – current USP<661>

Test scope is to measure the amount of non-volatile residual released by the cartridge treated with WFI water. The extraction tests were run in static conditions for 24 hours at 70 °C. A portion of liquid extracted was evaporated to dryness and then submitted to non-volatile residual (NVR) measure.

NVR test results are reported in table 6.

LOT N°	NVR
3104/03	<5 mg
5750/09	<5 mg
5606/55	<5 mg

Table 6-Results of tests carried out according to cUSP<661>

FilterPES 0.2 micron meet USP<661> requirements.

Biological Safety Test

➤"In vitro" Biological Reactivity Test - Class VI Plastic Materials (cUSP<87>)

Test scope is to evaluate biological toxicity of FilterPES cartridges 0.2 micron . The cartridge (O-rings included) is submitted to extraction with extractive solutions following related recipes provided for by current USP <87>. Test results are recorded as reactivity degree ranging from 0 (none reactivity) to 4 (high reactivity)

LOT N°	TEST	METHOD	RESULTS
3104/03	cytotoxicity	cUSP <87>	Reactivity grade = 0
6945/45	cytotoxicity	cUSP <87>	Reactivity grade = 0
5831/53	cytotoxicity	cUSP <87>	Reactivity grade = 0

Table 7-Results of tests carried out according to current USP<87>

Test results carried out according to USP<87>,.demonstrate lack of "in vitro" biological reactivity by FilterPES filter cartridges 0.2 micron rated.

➤"In Vivo" Biological Reactivity Test - Class VI Plastic Materials – Safety Test (cUSP<88>)

Test scope is to evaluate the "in vivo" reactivity of FilterPES cartridge according to the method provided for by USP <88>.
Test results are compared with USP acceptability limits.
The results are reported in the table.

LOT N°	TEST	RESULTS
3104/58	Intracutaneous Test	Conform
	Systemic Injection Test	Conform
	Implantation Test	Conform
6945/19	Intracutaneous Test	Conform
	Systemic Injection Test	Conform
	Implantation Test	Conform
5831/11	Intracutaneous Test	Conform
	Systemic Injection Test	Conform
	Implantation Test	Conform

Table 8-Results of the tests carried out according current USP<88>

Test results carried out according to USP<88>,.demonstrate lack of "in vvo" biological reactivity by FilterPES filter cartridges 0.2 micron rated.

Physical characteristics

➤Hydraulic stress test

Test purpose is to demonstrate the capability of FilterPES 0.2 micron cartridges to tolerate hydraulic stress at ambient temperature (20±5 °C). 10" FilterPES cartridges were installed inside an holder, wetted with water and fluxed at 2 bar during 20 minutes at least. After the wetting cycle was run a diffusion test.
If the cartridge passes the diffusion test, is then washed with a direct flux during 10 minutes, with 50 sudden pressure strokes from 0 to 5.0 bar. The same cartridge is then back-flushed at 2.0 bar per 10 minutes, with 50 sudden pressure strokes from 0 to 5.0 bar.
This test is repeated 50 times in both flux directions- Every 10 stress cycle every single cartridge is controlled by integrity diffusion test.
Diffusion test is performed at 2200 mbar. Acceptability limit of diffusion test was set at 22.0 mL/min. The following table reports diffusion test results run before and after the stress test.

LOT N°	DIFFUSION BEFORE STRESS TEST (mL/min)	DIFFUSION AFTER STRESS TEST (mL/min)
6644/45	16.0	15.5
6644/34	17.0	18.0
6644/18	16.0	17.5
6544/46	15.0	16.0
6544/12	15.0	16.5
6733/03	17.5	18.5
6945/43	14.5	15.5
6544/21	15.5	16.5
7045/53	17.5	19.5

Table 9-Results of hydraulic stress test run on FilterPES filter cartridges

Test results confirm the high resistances of FilterPES filter cartridges to hydraulic stress, even changing pressure and flux direction.

Thermal stress test

The purpose of this test is to determine FilterPES filter cartridges (10") resistance to multiple steam sterilization. The test has been carried out at 121 °C as provided for an appropriate steam sterilization. After a diffusion test the cartridge is submitted to 50 sterilization cycles. Every 10 cycles diffusion test i repeated.
Sterilization cycles follow the schedule below

STEP	TEMPERATURE (°C)	PRESSURE (bar)
STERILIZZATION	121±1	1.14±0.04
WARM UP	121→96	1.12→0.00

Table 10-Sterilising cycle program

Diffusion tests was run at 2200 mbar with a limit of acceptability of 22.0 mL / min. The results are reported in the following table
:

LOT N°	DIFFUSION BEFORE STRESS TEST (mL/min)	DIFFUSION AFTER STRESS TEST (mL/min)
6644/01	16.0	18.5
6644/09	17.0	18.5
6644/11	16.0	17.5
6544/33	14.0	16.0
6544/41	15.0	16.5
6733/05	16.0	17.0
6945/17	15.8	18.0
6544/44	15.5	16.5
7045/28	16.5	17.5

Table 5-FilterPES cartridges Thermal Stress Test results

Test results confirm the high resistance to thermal stress of FilterPES cartridges.

Differential pressure vs water flow rate

The test measures the pressure drop when different flow rates are fluxed across the filter cartridge membrane.
All data are referred to temperature of 20±5 °C.
10" FiterPES cartridges typical pressure drop vs flow rate curve, is shown in the following graph.
Within the typical flow rate range of usage, FilterPES cartridges guarantee initial pressure drops less than 0.2 bar (flow rate <1200 L/h per 10" cartridge)

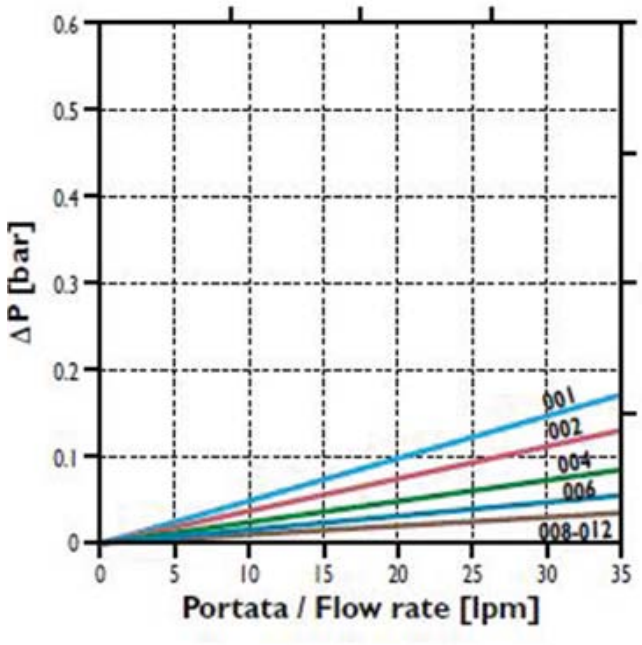


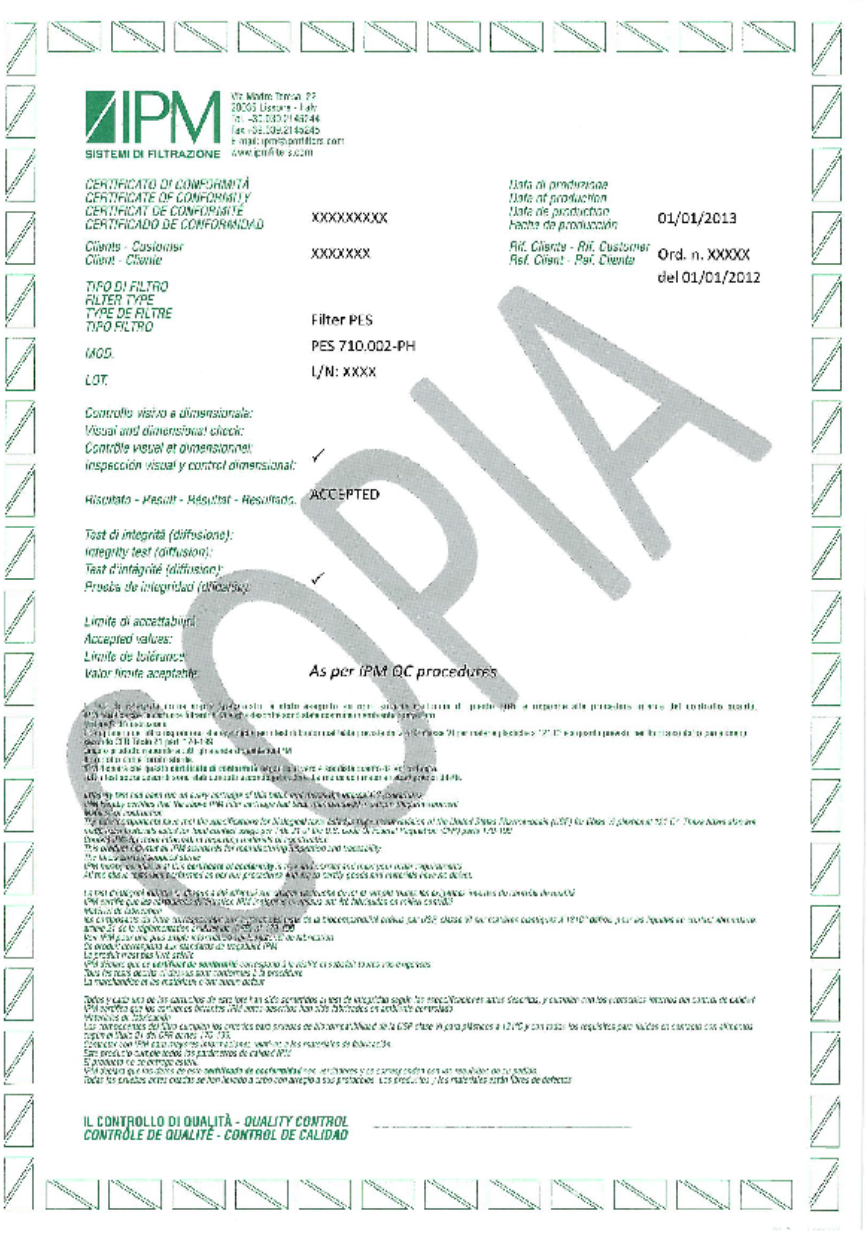
Figure 4-Water Flow Rate vs pressure drop graph.

PES	D	10	002	S	I	PH
Product identification **PES**	Cartridge type	Lenght	Filtration Rating	Gaskets O-rings	Insert	Version
	D = DOE (Double Open End) **2** = bayonet 2.226/flat **3** = 2.222/flat **5** = 3 bayonet 2.222/tip **7** = bayonet 226/tip **8** = 2.222/tip	10=10" 20=20" 30=30" 40=40"	002= 0,2 µm 004 = 0,45 µm 006 = 0,65 µm 008 = 0,8 µm 012 = 1,2 µm	B = Buna N E = EPDM S = Silicone V = Viton X = other* * Contact IPM	I = with SS insert (*) 0 = W/o SS insert (*) When filter has to be sterilised by steam	PH= Pharma Version
	J = JUNIOR cartridge	02=2.5" 05=5"				

Attachment

➢ Sample of Certificate of Conformity enclose in every packaging of cartridge type –PH

Every cartridge type –PH (which can be used in pharmaceutical productions) is shipped together with a Conformity Certificate (CoC) / Lot traceability. Here following a facsimile:



IPM SISTEMI DI FILTRAZIONE

CERTIFICATO DI CONFORMITÀ
CERTIFICATE OF CONFORMITY
CERTIFICAT DE CONFORMITE
CERTIFICADO DE CONFORMIDAD — XXXXXXXXX

Data di produzione / Date of production / Date de production / Fecha de producción — 01/01/2013

Cliente - Customer / Client - Cliente — XXXXXXX

Rif. Cliente - Ref. Customer / Réf. Client - Ref. Cliente — Ord. n. XXXXX del 01/01/2012

TIPO DI FILTRO / FILTER TYPE / TYPE DE FILTRE / TIPO FILTRO — Filter PES

IMOD. — PES 710.002-PH

LOT. — L/N: XXXX

Controllo visivo e dimensionale: / Visual and dimensional check: / Contrôle visuel et dimensionnel: / Inspección visual y control dimensional: — ✓

Risultato - Result - Résultat - Resultado — ACCEPTED

Test di integrità (diffusione): / Integrity test (diffusion): / Test d'intégrité (diffusion): / Prueba de integridad (difusión): — ✓

Limite di accettabilità / Accepted values: / Limite de tolérance / Valor límite aceptable — As per IPM QC procedures

COPIA

IL CONTROLLO DI QUALITÀ - QUALITY CONTROL
CONTRÔLE DE QUALITÉ - CONTROL DE CALIDAD

Figure 5- Sample of Conformity Certificate released by IPM Sistemi di Filtrazione

IPM Sistemi di Filtrazione s.r.L – Via Madre Teresa, 22 -20851 Lissone (MB) - ITALY

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