

Datwyler Pharma Packaging Belgium NV

QUALITY CERTIFICATE

The products identified below are in agreement with the dimensions and tolerances as specified on the relevant Datwyler Pharma Packaging product drawing and consistent of material conforming to Datwyler Pharma Packaging's specifications for the indicated compound.

They meet the "Type I" requirements of the European Pharmacopoeia, 3.2.9 and USP <381> current edition as delivered.

The applied washing program has been validated to meet applicable requirements of the FDA 2004 "Guidance for industry, Sterile Drug Products produced by Aseptic Processing" and the requirements of the EMEA 2002 "Note for Guidance on Quality of Water for Pharmaceutical Use". Initial rinses have been performed with Purified Water, meeting requirements of USP and Pharm. Eur., current version.

The last rinsing has been performed with "Water for Injection" meeting the requirements of the current version of USP and Pharm. Eur..

The products have been packed in a clean controlled environment in dedicated bags with visible underpressure between the primary and the secondary bag.

The products have been packed in dedicated bags with visible vacuum between the two sealed outer bags. This visible vacuum is to be used as indicator for pack integrity. Products must not be used if no visible vacuum is present between these two sealed outer bags.

The products have subsequently been sterilized using a validated Gamma Irradiation process applied by an approved subcontractor. The process has been validated according to ISO 11137 'Sterilization of health care products - Radiation' and is maintained in a validated state using routine controls.

The validated dose guarantees that a sterility assurance level of at least 10^{-6} is obtained.

IDENTIFICATION DATA

Product	: PLUNGER PREFILLED SYRINGE	Batch	: 30615936
Product number	: V9258	Quantity delivered	: 71,500 KPC
Compound	: FM257/2 DARK GREY	Packing date	: Apr 03, 2013
Final treatment	: ISAF2	Weighing run number(s)	: 3060523457
			3060523458
			3060523459
			3060523460

IN-PROCESS CONTROL DATA**Compliance with in-house specification (for w.r. numbers)!!!**

Test	Test object	Units	Compound specification	Found
DENSITY	TEST PIECE	g/cm ³	1,330 to 1,380	1,357 1,357 1,357 1,353
HARDNESS	TEST PIECE	deg. shore A	47 to 57	51 51 51 51

Compliance with EP chemical testing (for weighing run on in-process control test pieces pre-gamma irradiation)

Test	Test object	Units	Limit	Found
Opalescence	solution S	NTU	6,00	0,30
Colour	solution S	GY5	5,00	pass
Acidity (EP)	20 ml S	ml 0,01 M NaOH	0,30	0,03
Acidity (USP)	20 ml S	ml 0,01 M NaOH	0,30	0,00
Absorbance	solution S	max abs 220-360 nm	0,20	0,01
Reducing subst.	20 ml S	ml 0,002 M KMnO ₄	3,00	0,15
Heavy metals	solution S	ppm Pb	2,00	pass
Extractable zinc	solution S	ppm Zn	5,00	0,00
Ammonium	solution S	ppm NH ₄	2,00	pass
Volatile sulfides	20 cm ²	mg Na ₂ S	0,05	pass
Residue	50 ml S	mg	2,00	0,00

G. Droogmans, Quality Control Manager

DATE: Apr 24, 2013

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QUALITY CERTIFICATE

Product : V9258

Compound : FM257/2 DARK GREY

Batch : 30615936

FINISHED PRODUCT INSPECTION DATA**Compliance with in-house specification**

Test	Test Frequency	Sample Size	AQL	Units	Limit	Found
Total Height	Each batch	50	1,000	Piece	1	0
Major A defects	Each batch	500	0,250	Piece	3	0
Major B defects	Each batch	500	0,650	Piece	7	0
Minor defects	Each batch	500	2,500	Piece	21	3

Particle Counting

Test	Test Frequency	Sample Size cm ²	Units	Found
Particle counting 2-5µm	Each batch	100	part/10 cm ²	507
Particle counting 5-10µm	Each batch	100	part/10 cm ²	166
Particle counting 10-25µm	Each batch	100	part/10 cm ²	29
Particle counting 25-50µm	Each batch	100	part/10 cm ²	1
Particle counting 50-100µm	Each batch	100	part/10 cm ²	0,4
Particle counting >100µm	Each batch	100	part/10 cm ²	0,2

Compliance with in-house microbiological requirements

Test	Test Frequency	Sample Size	Units	Limit	Found
Endotoxin unit	Each batch	21	EU/product	1,00	0,00
Bioburden	Each batch	42	CFU/product	1,50	0,31

Compliance with customer requirements

Test	Frequency	Limit	Pass/Fail
Certificate of irradiation	Each batch	>25<40kGy	PASS

The full report on dimensional data is attached.

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QUALITY CERTIFICATE : ATTACHMENT**Product** : V9258**Compound** : FM257/2 DARK GREY**Batch** : 30615936**FINISHED PRODUCT INSPECTION DATA****Compliance with in-house specification****Total Height** values in mm.

Specification : 7,70 +0,40 mm -0,40 mm

Results of 50 products : Average : 7,84 mm
Range : from 7,72 to 7,93 mm
Outside tolerance : 0
Standard deviation : 0,050

Class mean	Frequency
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Smaller than 7,30	0
7,30	0
7,35	0
7,40	0
7,45	0
7,50	0
7,55	0
7,60	0
7,65	0
7,70	2
7,75	8
7,80	18
7,85	14
7,90	8
7,95	0
8,00	0
8,05	0
8,10	0
Greater than 8,10	0

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