

## 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 consist 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 are performed with Purified Water, meeting the requirements of USP and Pharm. Eur., current valid version.

The last rinsing has been performed with "Water for Injection" meeting the requirements of the current valid version of USP and Pharm. Eur.. The products have been packed in a clean controlled environment.

**IDENTIFICATION DATA**

<b>Product</b>	: LYO STOPPER	<b>Batch</b>	: 30539491
<b>Product number</b>	: V9172	<b>Quantity delivered</b>	: 51,200 KPC
<b>Compound</b>	: FM460/0 DARK GREY	<b>Packing date</b>	: Feb 08, 2013
<b>Final treatment</b>	: ISAF1	<b>Weighing run number(s)</b> :	3053562945
			3053562946
			3053562947
			3053562948

**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 <sup>3</sup>	1,323 to 1,373	1,347 1,349 1,351 1,347
HARDNESS	TEST PIECE	deg. shore A	41 to 51	45 46 45 46

**Compliance with Physicochemical tests EP 3.2.9 and USP <381>**

Test	Test object	Units	Limit	Found
Opalescence	solution S	NTU	6,00	0,70
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 <sub>4</sub>	3,00	0,45
Heavy metals	solution S	ppm Pb	2,00	pass
Extractable zinc	solution S	ppm Zn	5,00	0,00
Ammonium	solution S	ppm NH <sub>4</sub>	2,00	pass
Volatile sulfides	20 cm <sup>2</sup>	mg Na <sub>2</sub> S	0,05	pass
Residue	50 ml S	mg	2,00	0,00

G. Droogmans, Quality Control Manager

DATE: Apr 24, 2013

PAGE 2 / 9

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**QUALITY CERTIFICATE**

Product : V9172

Compound : FM460/0 DARK GREY

Batch : 30539491

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

Test	Test Frequency	Sample Size	AQL	Units	Limit	Found
Flange thickness	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	5

**Particle Counting**

Test	Test Frequency	Tested Batch	Sample Size cm <sup>2</sup>	Units	Found
Particle counting 2-5µm	Each batch	30539491	100	part/10 cm2	525
Particle counting 5-10µm	Each batch	30539491	100	part/10 cm2	150
Particle counting 10-25µm	Each batch	30539491	100	part/10 cm2	14
Particle counting 25-50µm	Each batch	30539491	100	part/10 cm2	0
Particle counting 50-100µm	Each batch	30539491	100	part/10 cm2	0,2
Particle counting >100µm	Each batch	30539491	100	part/10 cm2	0,0

**Compliance with in-house microbiological requirements**

Test	Test Frequency	Sample Size	Units	Limit	Found
Endotoxin unit	Each batch	9	EU/product	1,00	0,00
Bioburden	Each batch	18	CFU/product	2,00	0,00

**Compliance with functionality tests EP 3.2.9 and USP <381>**

Test	Test Frequency	Tested Batch	Sample Size	Units	Limit	Found
Penetrability	1 in 10 Batches	30433617	10	N	10,00	3,90
Fragmentation	1 in 10 Batches	30433617	48	Fragments	5,00	1,00
Self-sealing	1 in 10 Batches	30433617	100	Nr. Of Leaks	0,00	0,00

The full report on dimensional data is attached.

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PAGE 3 / 9

## Datwyler Pharma Packaging Belgium NV

**QUALITY CERTIFICATE : ATTACHMENT****Product** : V9172**Compound** : FM460/0 DARK GREY**Batch** : 30539491**FINISHED PRODUCT INSPECTION DATA****Compliance with in-house specification****Flange thickness** values in mm.

Specification : 3,30 +0,25 mm -0,25 mm

Results of 50 products : Average : 3,32 mm  
Range : from 3,21 to 3,44 mm  
Outside tolerance : 0  
Standard deviation : 0,060

Class mean	Frequency
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Smaller than 3,05	0
3,05	0
3,10	0
3,15	0
3,20	5
3,25	9
3,30	24
3,35	5
3,40	7
3,45	0
3,50	0
3,55	0
Greater than 3,55	0

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PAGE 4 / 9