

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.

IDENTIFICATION DATA

Product	: LYO STOPPER	Batch	: 30552137
Product number	: V9250	Quantity delivered	: 92,153 KPC
Compound	: FM157/2 DARK GREY	Packing date	: Feb 08, 2013
Final treatment	: ISAF1	Weighing run number(s)	: 3055024417

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	1,285 to 1,335	1,303
HARDNESS	TEST PIECE	deg. shore A	40 to 50	44

Compliance with Physicochemical tests EP 3.2.9 and USP <381>

Test	Test object	Units	Limit	Found
Opalescence	solution S	NTU	6,00	0,50
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	0,02
Reducing subst.	20 ml S	ml 0,002 M KMnO ₄	3,00	0,35
Heavy metals	solution S	ppm Pb	2,00	pass
Extractable zinc	solution S	ppm Zn	5,00	0,01
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	0,20

G. Droogmans, Quality Control Manager

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Product : V9250

Compound : FM157/2 DARK GREY

Batch : 30552137

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	4

Particle Counting

Test	Test Frequency	Tested Batch	Sample Size cm ²	Units	Found
Particle counting 2-5µm	1 in 10 Batches	30545458	100	part/10 cm2	583
Particle counting 5-10µm	1 in 10 Batches	30545458	100	part/10 cm2	198
Particle counting 10-25µm	1 in 10 Batches	30545458	100	part/10 cm2	18
Particle counting 25-50µm	1 in 10 Batches	30545458	100	part/10 cm2	2
Particle counting 50-100µm	1 in 10 Batches	30545458	100	part/10 cm2	0,5
Particle counting >100µm	1 in 10 Batches	30545458	100	part/10 cm2	0,3

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	30545458	10	N	10,00	2,80
Fragmentation	1 in 10 Batches	30545458	48	Fragments	5,00	2,00
Self-sealing	1 in 10 Batches	30545458	100	Nr. Of Leaks	0,00	0,00

The full report on dimensional data is attached.

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QUALITY CERTIFICATE : ATTACHMENT**Product** : V9250**Compound** : FM157/2 DARK GREY**Batch** : 30552137**FINISHED PRODUCT INSPECTION DATA****Compliance with in-house specification**

Flange thickness values in mm.

Specification : 2,00 +0,20 mm -0,20 mm

Results of 50 products : Average : 2,02 mm
Range : from 1,87 to 2,10 mm
Outside tolerance : 0
Standard deviation : 0,040

Class mean	Frequency
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Smaller than 1,80	0
1,80	0
1,85	1
1,90	1
1,95	13
2,00	22
2,05	12
2,10	1
2,15	0
2,20	0
Greater than 2,20	0

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