

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	: SERUM STOPPER	Batch	: 30585951
Product number	: V9048	Quantity delivered	: 167,124 KPC
Compound	: FM257/2 DARK GREY	Packing date	: Mar 13, 2013
Final treatment	: SAF1	Weighing run number(s)	: 3058280245 3058280246 3058280247 3058280248

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	1,354 1,354 1,355 1,358
HARDNESS	TEST PIECE	deg. shore A	47 to 57	49 50 49 50

Compliance with Physicochemical tests EP 3.2.9 and USP <381>

Test	Test object	Units	Limit	Found
Opalescence	solution S	NTU	6,00	1,10
Absorbance	solution S	max abs 220-360 nm	0,20	0,02

G. Droogmans, Quality Control Manager

DATE: Apr 24, 2013

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