

Quality Certificate

The products identified below are in agreement with the dimensions and tolerances as specified on the relevant Helvoet Pharma product drawing and consist of material conforming to Helvoet Pharma's specification for the indicated compound. They meet the 'Type I' requirements of the valid version of the European Pharmacopoeia Section 3.2.3.

Identification data

Product	: Infusion stopper 20 mm	Lot number	: CH0333131	Weighing Run number	: M01539022
Product number	: V 9025	Lot subnumbers	: 17 18 19 20	Mixing Run Number	: M01539166
Compound	: FM257/2	Packing date	: Oct 06, 2016.	Quantity Delivered	: 12000 pieces
Final treatment	: SAF1/IE10	Description	: Each box contains 1 single sealed PE-bag		
Packing code	: 1E10				
Pcs. per inner bag	: 7000				

In-process control data

a. Compliance with the in-house specifications, for the quoted sublots.

Method	Test Object	Units	Compound specification	Found			
Density	test piece	g/ml	1.330 to 1.380	1.358	1.349	1.352	1.355
Hardness	test piece	deg. Shore A	47 to 57	50	49	49	49

b. Compliance with physico-chemical specification for Weighing Run M01539022.

Tests for opalescence and absorbance are conducted on a water extract as per the European Pharmacopoeia.

Test	Test Object	Units	Limit	Found
Opalescence	solution S	NTU	6	1
Absorbance	solution S	Max abs. in r. 220-360nm	0.20	pass