

TEST RESULT REPORT

TE192081/ 19-B7742

Material: PET RESIN (RAMAPET N2-N1-S1)

LOT: N/A

TESTS ON POLYETHYLENE TEREPHTHALATE FOR CONTAINERS FOR PREPARATIONS NOT FOR PARENTERAL USE– EP 3.1.15 - 9TH EDITION 2019 (9.8)

CHAPTER 3.1.15

Client: I.V.L DHUNSERI POLYESTER COMPANY S.A.E

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Client Purchase Order Number: PL/2019/SR/00851

Quotation Number: 1906006

Date Receipt Samples: 09 Aug 2019

Date Start Analysis: 12 Sep 2019

Date Technical Release: 25 Sep 2019

Date Final Test Result Report: 30 Sep 2019

REFERENCES:

European Pharmacopoeia 9th Edition 2019 (9.8), "Polyethylene Terephthalate for Containers for Preparations not for Parenteral Use", Chapter 3.1.15, Section "Tests".



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RESULTS:

The results are presented in Table 1.

Table 1: Results of Analysis

Test	Results	Evaluation Criteria	Meets Criteria
Appearance of Solution: Turbidity on S1	\leq RSI 3NTU	Turbidity \leq RSI 3NTU	PASS
Appearance of Solution: Turbidity on S2	\leq RSI 3NTU	Turbidity \leq RSI 3NTU	PASS
Appearance of Solution: Coloration on S2	Clear, no color	Color \leq RS B ₉	PASS
Acidity on S1	+ 0.5 mL 0.01M NaOH → turns blue	Not more than 0.5 mL of 0.01M of NaOH is required to change the color of the indicator to blue	PASS
Alkalinity on S1	+ 0.5 mL 0.01M HCl → yellow turns orange	Not more than 0.5 mL of 0.01M HCl is required to change the color of the indicator to orange	PASS
Absorbance on S1	\leq 0.2 A.u.	220nm to 340nm Absorbance \leq 0.2 A.u.	PASS
Absorbance on S2	\leq 0.05 A.u.	400nm to 800nm Absorbance \leq 0.05 A.u.	PASS
Reducing Substances on S1	\leq 0.5 mL	Difference between Blank and Test Solution \leq 0.5 mL	PASS
Substances soluble in Dioxane	\leq 30 mg	Max 3%: Residue \leq 30 mg	PASS
Sulphated Ash	\leq 0.5 %	\leq 0.5 %	PASS

Test	Results	Evaluation Criteria	Meets Criteria
Extractable Aluminum (S3)	≤ 1 mg/L	≤ 1 mg/L	PASS
Extractable Barium (S3)	≤ 1 mg/L	≤ 1 mg/L	PASS
Extractable Cobalt (S3)	≤ 1 mg/L	≤ 1 mg/L	PASS
Extractable Manganese (S3)	≤ 1 mg/L	≤ 1 mg/L	PASS
Extractable Titanium (S3)	≤ 1 mg/L	≤ 1 mg/L	PASS
Extractable Zinc (S3)	≤ 1 mg/L	≤ 1 mg/L	PASS
Extractable Germanium (S4)	≤ 1 mg/L	≤ 1 mg/L	PASS
Extractable Antimony (S4)	≤ 1 mg/L	≤ 1 mg/L	PASS

CONCLUSION:

Based on the evaluation criteria mentioned above, the test material meets the requirements of the European Pharmacopoeia 9th edition 2019 (9.8), Chapter 3.1.15: “Polyethylene Terephthalate for Containers for Preparations not for Parenteral Use”, section “Tests”.