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TESTS ON PLASTIC MATERIALS AND COMPONENTS USED TO PACKAGE MEDICAL ARTICLES ACCORDING TO UNITED STATES PHARMACOPOEIA 31 *NF 26* GENERAL CHAPTERS: 661 SECTION "PHYSICOCHEMICAL TESTS".

TM 4 MED

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1.0 OBJECTIVE OF THE STUDY

The aim of this study was to investigate if the test material meets the requirements of the United States Pharmacopoeia regarding the General Chapter 661 for plastic materials used to package medical articles as directed under *Physicochemical Tests* in the section *Test Methods*.

2.0 REFERENCES

The study is conducted based upon the United States Pharmacopoeia 31 *NF 26*, General Chapter 661 "Containers & Plastics".

3.0 TEST MATERIAL IDENTIFICATION

The following information was supplied by the Sponsor on a test registration form or other correspondence wherever applicable; it does not apply to confidential information.

Test Material Name: **TM 4 MED**
CAS/Code: N/S
Lot/Batch: N/S
Physical State: Solid
Color: N/S
Stability: N/S
Solubility: N/S
Storage Conditions: **Ambient conditions**
Safety Precautions: N/S

4.0 EXPERIMENTAL DESIGN.

4.1 Testing Parameters

Extraction Medium – Ultra Purified Water (UPW) was used as the *Extraction Medium*, maintained at a temperature of 70°C during the extraction of the *Sample Preparation*.

Blank – UPW was used in the tests were a blank is specified.

Sample Preparation – 670 cm^2 of the Test Item was cut into pieces of ± 0.5 cm^2 and transferred to a glass-stoppered, 250 mL extraction flask. The sample was washed twice with 150 mL of UPW.

Sample Preparation Extract – To the prepared sample, 112 mL of *Extraction Medium* was added. The sample was extracted by heating in a water bath at the temperature specified for the *Extraction Medium* for 24 hours. After the extraction the extract was cooled, but not below 20°C.

4.2 Nonvolatile residue

50.0 mL of the *Sample Preparation Extract* and the *Blank* were transferred to a suitable, tared crucible and evaporated till dryness on a hot plate. After the evaporation, the extract and the blank were further dried in an incubator oven at 105 ± 1°C for one hour.
The difference between the residues obtained from the *Sample Preparation Extract* (2.1 mg) and the *Blank* (0.0 mg) is 2.1 mg. (Limit is 15 mg)

4.3 Residue on Ignition

It was not necessary to perform this test since the *nonvolatile residue* test result did not exceeded 5 mg.

4.4 Heavy Metals

20.0 mL of the *Sample Preparation Extract* was transferred into one of two matched 50-mL color comparison tubes. The pH was adjusted between 3.0 and 4.0 with 1 N acetic acid. The extract was further diluted to 35 mL with UPW and mixed.

Into a second color comparison tube 0.2 mL of *Lead Stock Solution (100 ppm)* and 20.0 mL of the *Blank* were added and the pH was adjusted between 3.0 and 4.0 with 1 N acetic acid. The mixture was further diluted to 35 mL with UPW and mixed.

To both tubes 1.2 mL of thioacetamide-glycerin base TS and 2 mL of pH 3.5 Acetate Buffer were added. Both tubes were mixed and further diluted to 50 mL with UPW.

After 10 minutes there was no color produced in the tube containing the *Sample Preparation Extract* and thus the color did not exceeded the color produced in the tube containing the *Standard Lead Solution* as they were viewed downward over a white surface. This indicates that the concentration of heavy metals in the extract was less than 1 ppm.

4.5 Buffering Capacity

20 mL of the *Sample Preparation Extract* was titrated to a pH of 7.0, using 0.1 mL of 0.01 N Sodium Hydroxide. The *Blank* was titrated to a pH of 7.0, using 0.1 mL of Hydrochloric Acid. The difference between the two titrated volumes was 0.2 mL. (Limit is 10.0 mL)

5.0 Summary of Results

The results and the evaluation criteria for the different tests performed in this report are listed below.

TEST	TEST RESULT	EVALUATION CRITERIA	PASS/ FAIL
Nonvolatile Residue	2.1 mg	15 mg	PASS
Residue on Ignition	N/A	N/A	N/A
Heavy Metals	No color (< 1 ppm)	Color is less intense than color of the *Standard Lead Solution*	PASS
Buffering Capacity	0.2 mL	< 10 mL	PASS

6.0 Conclusion

Based on the evaluation criteria mentioned above, the test material, "**TM 4 MED" meets** the requirements of the United States Pharmacopoeia Current version, General Chapter 661 section "Physicochemical Tests".