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Pharmaceutical Coating System

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QUALITY CONTROL					
Doc. No.	AEPL/20-21/TM003	Rev No.		Copy No.	
TITLE	Test Method - TabSafe Uni (Film Coating Material)				
Effective Date :11/07/2020		Next Review Schedule:July2022			

Approvals			
	Designation	Signature	Date
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Prepared By	Manager- Q.C Mohanty A.	Mohanty	11/07/2020

Change Control No.	Not Applicable

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I **Apperance:**

Take 5.0 gm sample in a clean and dry petri plate. Check the Physical apprearance

II **PH**

Check pH of the solution prepared for viscosity

III **Particle Size**

Weigh a stainless steel sieve having 100um opening OR suitable single woven wire cloth with a mesh width of 100um,and filter 100grams of the solution prepared for viscosity through it. Wash the sieve or the cloth with suitable solvent unit a clear filtrate is obtained, and dry the Sieve or the cloth to constant weight at 110 degree C

IV **Identification**

Mix 10.0 grams of sample with 0.3 grams of Triethyl citrate,pour on a glass slide and allow the water to evaporate.

V **Viscosity**

Take 150grams IPA and 300 grams Methyl Dichloride in a conical flask. Add 45 grams of Tab Safe Uni Powder while stirring by the means of magnetic stirrer. Close the flask and continue stirring for 30 another min. Adjust the temperature to 25 degree C with the spindle rotating at 30 rpm. Equip a suitable rotational viscometer with spindle having cylinder 1.88 cm in diameter and 6.25 cm high,attached to a shaft 3.2 mm in diatmeter. The distance from the top of a cylinder to the lower tip of the shaft is 7.5 mm and the immersion depth being 8.15 cm, immediately observe and record the scale reading.

VI **Loss on drying**

Weigh a glass petridish that has been previously dried for 30 min. in hot air oven at 110 degree C and cool in a dessicator for 15 min. (W1).Transfer to the petridish about 1.0 to 2.0 gms of the sample and accurately weigh it (W2). Distribute the sample as evenly as possible by gentle sidewise shaking to a depth of not exceeding 10 mm. Place the loaded petridish in the drying oven at 110 degree C. Dry the Sample for 2 hours. After drying is complete, open the drying chamber and allow it to cool to room temperature in desiccators before weighing.Weigh the petridish and the contents (W3).

Calculations:

Loss on drying = (W2-W3/W2-W1)X 100

Where :

W1 = Weight of container

W2 = Weight of the Container + Sample before Drying

W3 = Weight of the Container + Sample after Drying

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VII **Arsenic**

Arsenic trioxide stock solution :

Dissolve 132.0 mg of Arsenic trioxide. Previously dried at 105 degree C for 1 hour and accurately weigh, in sodium hyroxide solution (1 in 5 ml) in a 1000 ml volumetric flask. Neutralise the solution with 2N Sulphuric acid, add 10 ml more 2 N Sulphuric acid the add recently boiled and water to volume and mix.

Standard Arsenic Solution :

Transfer 10 ml of Arsenic trioxide solution to a 1000 ml of volumetric flask,add 10 ml of 2N Sulphuric acid , then add recently boiled and cooled water to volume, and mix.Each ml of standard Arsenic Solution contains the equivalent container, and use it within 3 days.

Standard preparation :

Pipette 1.5 ml standard Arsenic Solution into a graduated flask and dilute with water to 35 ml

Test preparation :

Take 1.5 ml of sample in generator flask dissolve in water, and dilute with water to 35 ml.

Procedure :

Add 20 ml of 7 N Sulphuric acid, 2 ml of potassium Iodide, 0.5 ml stronger acid stannous chloride TS and 1 ml IPA and mix. Allow to stand at room temperature for 30 minutes. Pack the scrubber tube (c) with two pledgets of cotton that have been soaked in saturated lead acetate solution,freed from excess solution by expression,and dried in vaccum at room temperature leaving a 2 mm space between two pledgets. Lubricate the joints with a suitable stopcock grease designated for use with organic solvents and connect the scrubber unit to the absorbent tube. Transfer 3.O ml o f silver dierhydithiocarbamate TS to the absorber tube. Add 3.0 g of granular Zinc to the mixture in the flask, immediately connect the assembled scrubber unit, and allow the evolution of hyrogen and the color development to proceed at room temperature for 45 mins, swirling the flask gently at 10 min intervals. Disconnect the absorbing tube from generator and scrubber units, and transfer the absorbing solution to a 1 cm absorption cell. Any red color produced by the test preparation does not exceed that produced by standard preparation. If required determine the absorbance between 535 and 540 mm, with a suitable spectrophotometer using silver diethyldithiocarbamate TS as the blank.

VIII **Heavy Metals :**

Preparation of pH 3.5 Acetate Buffer :

Dissolve 25.0 g of ammonium acetate in 25 ml of water, and add 38 ml of 6 N hyrochloric acid. Check pH and if necessary adjust pH with 6 N hydrochloric acid. Dilute with water to 100 ml and Mix.

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Lead nitrate stock solution :

Dissolve 159.8 mg of lead nitrate in 100 ml water containing 1 ml of nitric acid. Then dilute with water up to 1000 ml. Prepare and store this solution in glass containers from soluble lead salts.

Standard lead solution :

On the day of use, dilute 10 ml lead nitrate stock solution with water to 100 ml Each ml of 10 ug of pb

Standard prepatation :

Take 2 ml of standard lead solution (20ug of pb) in clean and dry 50ml color comparision tube. Dilute with 25 ml of water. Check pH of solution with the use of pH meter or short range pH indicator Paper.Adjust pH between 3 to 4 with 1N acetic acid or 6 N ammonium hydroxide. Dilute with water to 4 ml and mix well

Test preparation:

Accurately weigh 1 g of sample in clean and dry crucible, evaporate dispersion to dryness, add suffcient sulphuric acid to wet the substance, and carefully,ignite at low temperature untill thoroughly charred. Add 2 ml of nitric acid and 5 drops of sulphuric acid,and heat cautiously untill white fumes no longer are evolved.Cool, add 4 ml of 6 N hyrochloric acid cover, digest on a steam bath to dryness. Moisten the residue with 1 drop of hyrochloric acid, add 10ml of hot water, and digest for 2 minute.Add 6 N hyrochloric acid dropwise untill is just alkaline to litmus paper,dilute with water to 25 ml adjust with 1 N acetic acid to pH between 3.0 to 4.0 if necessary filter. Rinse the crucible and the filter with 10 ml of water, combine the filtrate and rinsing in a 50ml color comparision tube. Dilute with water to 40 ml and mix.

procedure :

To each tube containing the standard preparation and test preparation add 2 ml of pH 3.5 acetate buffer, the add 10 ml freshly prepared hydrogen sulfide TS to each of the tubes,dilute with water.To 50 ml , mix allows to stand for 5 minutes, and view downward over a white surface. The color of the solution from the test preparation is not darken is not darken that Standard prepatation.

IX **Bulk Density :**

Apparatus :

The apparatus consist of the following:

A 250ml graduated cylinder(readable to 2 ml with a mass of 220 + 44 g)

A setting Apparatus capable of producing,in a minute either nominally 250 + 15 Nominally 250 +15 taps from a height of 3+0.2 mm, or

nominally 300+15 taps from a heigh of 14+ 2 mm. The

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support for the graduated cylinder with its holder has a mass of 450 + 10 g

Procedure :

weight 10 g of material and transfer carefully in to the cylinder.
carry out 300 taps on the same powder sample and read the corresponding volumes graduated unit.
Calculate the tapped bulk density of the material as per formula given below :

$$\text{Bulk Density g/ml} = \frac{\text{Sample taken in gram}}{\text{Volume measured in ml}}$$

X **Color Difference :**

Visually match the color of sample with previous approved material.