



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### GENERAL TESTING PROCEDURE

**Title:** Limit Test for Arsenic

<b>SOP No.:</b>		<b>Department :</b>	QC
<b>Effective Date :</b>		<b>Review Date :</b>	
<b>Revision No.:</b>	00	<b>Page No.:</b>	1 of 3
<b>Supersede SOP No.:</b>	Nil		

#### 1.0 OBJECTIVE:

1.1 To lay down a procedure for limit test for Arsenic.

#### 2.0 SCOPE:

2.1 It is applicable for the estimation of Raw material.

#### 3.0 RESPONSIBILITY:

3.1 Analyst / Officer / Executive follow the procedure.

3.2 Head-QC are responsible for effective implementation of this SOP.

#### 4.0 REFERENCE:

4.1 Ph. Eur. method

#### 5.0 DEFINITION:

5.1 Arsenic is a chemical present in the environment as a naturally occurring substance and as a result of human activity. It is found in water, air, food and soil.

#### 6.0 PROCEDURE:

6.1 **METHOD A:** The apparatus (See Figure Below) consists of a 100 ml conical flask dosed with a ground-glass stopper through which passes a glass tube about 200 mm long and about 5 mm in internal diameter. The lower part of the tube tapers to an internal diameter of 1 mm, and about 20 mm from its tip is a lateral orifice 2-3 mm in diameter. When the tube is in position in the stopper, the lateral orifice is at least 3 mm below the lower surface of the stopper. A second glass tube of the same internal diameter is connected to the first tube. The second tube is bent twice at right angles and the free end of the tube tapers to an internal diameter of 1 mm. This end is immersed in a test-tube containing 3.0 ml of silver diethyldithiocarbamate solution. Other suitable equipment may be used. Into the first tube insert 50-60 mg of lead acetate cotton, loosely packed, or a small plug of cotton and 3. rolled piece of lead acetate paper weighing 50-60 mg. In the conical flask,



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

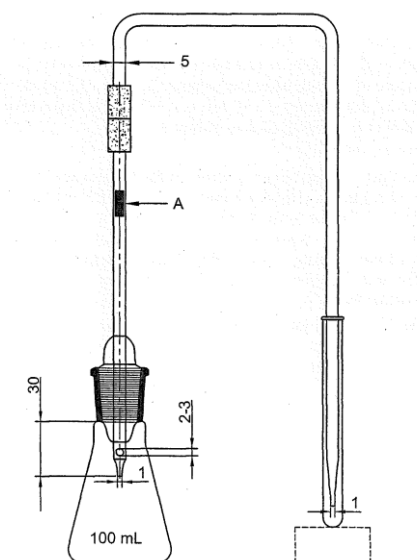
### GENERAL TESTING PROCEDURE

**Title:** Limit Test for Arsenic

<b>SOP No.:</b>		<b>Department :</b>	QC
<b>Effective Date :</b>		<b>Review Date :</b>	
<b>Revision No.:</b>	00	<b>Page No.:</b>	2 of 3
<b>Supersede SOP No.:</b>	Nil		

dissolve the prescribed quantity of the substance to be examined in 25 ml of water, or in the case of a solution adjust the prescribed volume to 25 mL with Water. Add 15 mL of hydrochloric acid, 0.1 ml, of stannous chloride solution and 5 ml of potassium iodide solution R, allow to stand for 15 min and introduce 5 g of activated zinc . Assemble the 2 parts of the apparatus immediately and immerse the flask in a water-bath at a temperature such that a uniform evolution of gas is maintained. Prepare a standard in the same manner, using 1 mL of arsenic standard solution (1 ppm As), diluted to 25 mL with water. If foaming occurs, 1 mL of 2-propanol R may be added to the flask. After at least 2 h, the colour obtained in the test-tube with the test solution is not more intense than that obtained with the standard.

**Suitability test:** The colour obtained in the test-tube with the standard is at least as intensely coloured as 3 mL of a mixture of 3.0 mL of yellow primary solution, 0.6 mL of red primary solution and 11.40 mL of a solution of hydrochloric acid (10 g/l HCl).



(A)Lead acetate paper/cotton

Apparatus for the limit test for arsenic (method A)



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### GENERAL TESTING PROCEDURE

**Title:** Limit Test for Arsenic

<b>SOP No.:</b>		<b>Department :</b>	QC
<b>Effective Date :</b>		<b>Review Date :</b>	
<b>Revision No.:</b>	00	<b>Page No.:</b>	3 of 3
<b>Supersede SOP No.:</b>	Nil		

**6.2 Method B:** Introduce the prescribed quantity of the substance to be examined into a test-tube containing 4 mL of hydrochloric acid and about 5 mg of potassium iodide and add 3 mL of hypophosphorous reagent. Heat the mixture on a water-bath for 15 min, shaking occasionally. Prepare a standard in the same manner, using 0.5 mL of arsenic standard solution (10 ppm As). After heating on the water-bath, the colour obtained in the test-tube with the test solution is not more intense than that obtained with the standard.

**7.0 Annexures:** NA

**8.0 Distribution:**

**8.1** Display copy 1: Quality Control Lab

**9.0 Abbreviation:**

GTP: General Test Procedure

QC: Quality Control laboratories

**10.0 Revision History:**

**10.1 Revision history table:**

Document Number	CC Number/Date	Brief Description of Change