

LOGO	----- (private)ltd
------	---------------------------

STANDARD OPERATING PROCEDURE

Title: **ALKALINITY OF GLASS**

SOP NO	DATED	EFFECTIVE	REVISION	REVIEW DATE	PAGES
/001	01 APRIL ,2013	26 APRIL,2013	2	APRIL ,2019	04(Four)
Replaces			NEXT REVIEW DATE		
SOP NO	Reviewed Date				
001	14 APRIL,2019		APRIL ,2023		

Written By: Analyst	Reviewed By: Microbiologist	Approved By: Q.C. Manager
Signature	Signature	Signature

DISTRIBUTION LIST

DISTRIBUTION	COPY#	COPY HOLDER

DOCUMENT REVISION HISTORY						
Rev NO.	Document change Request NO.	Description of Revision	Author	Reviewed By	Approved By	Effective Date
1		Not Applicable, Only Typographical Errors, and page number correction				

1. PURPOSE

It is established to check the quality of glass used for packing which is in direct contact with parenteral preparation.

2. SCOPE

It is applicable on the Quality Control department.

3. RESPONSIBILITY

Quality Control Analyst

Quality Control Manager

4. APPARATUS

4.1 AUTOCLAVE

For these tests, use an autoclave capable of maintaining a temperature of $121 \pm 2.0^\circ$, equipped with a thermometer, a pressure gauge, a vent cock, and a rack adequate to accommodate at least 12 test containers above the water level.

4.2 MORTAR AND PESTLE

Use a hardened-steel mortar and pestle.

4.3 OTHER EQUIPMENTS

Also required are 20.3-cm (8-inch) sieves made of stainless steel including the Nos. 20,40, and 50 sieves along with the pan and 250-mL conical flasks made of resistant glass aged as specified, a 900-g (2-lb) hammer, a permanent magnet, a desiccator, and adequate volumetric apparatus.

5. REAGENTS

5.1 HIGH-PURITY WATER

The water used in these tests has conductivity at 25° , as measured in an in-line cell just prior to dispensing, of not greater than 0.15 mS per cm (6.67 Megohm-cm). There must also be an assurance that this water is not contaminated by copper or its products (e.g., copper pipes, stills, or receivers).

5.2 METHYL RED SOLUTION

Dissolve 24 mg of methyl red sodium in purified water to make 100 ml. If necessary, neutralize the solution with 0.02 N sodium hydroxide or acidify it with 0.02 N sulfuric acid so that the titration of 100 ml of High-Purity Water, containing 5 drops of indicator, does not require more than 0.020 ml of 0.020 N sodium hydroxide to effect the color change of the indicator, which should occur at a pH of 5.6

6. CHEMICAL RESISTANCE—GLASS CONTAINERS

The following tests are designed to determine the resistance to water attack of new (not previously used) glass containers. The degree of attack is determined by the amount of alkali released from the glass under the influence of the attacking medium under the conditions specified. This quantity of alkali is extremely small in the case of the more resistant glasses, thus calling for particular attention to all details of the tests and the use of apparatus of high quality and precision. The tests should be conducted in an area relatively free from fumes and excessive dust.

6.1 Glass Types

Glass Types — Glass containers suitable for packaging Pharmacopeial preparations may be classified as in Table below on the basis of the tests set forth in this section. Containers of Type I borosilicate glass are generally used for preparations that are intended for parenteral administration. Containers of Type I

glass, or of Type II glass (i.e., soda-lime glass that is suitably dealkalized) are usually used for packaging acidic and neutral parenteral preparations. Type I glass containers, or Type II glass containers (where stability data demonstrate their suitability), are used for alkaline parenteral preparations. Type III soda-lime glass containers usually are not used for parenteral preparations, except where suitable stability test data indicate that Type III glass is satisfactory for the parenteral preparations that are packaged therein. Containers of Type NP glass are intended for packaging nonparenteral articles, i.e., those intended for oral or topical use

Glass Types and Test Limits

Type	General Description	Type of Test	Size	Limits ml of 0.02N H ₂ SO ₄
I	Highly resistant borosilicate glass	Powdered Glass	All	1.0
II	Treated soda-lime Glass	Water Attack	100 or less	0.7
			over 100	0.2
III	Soda-lime glass	Powdered Glass	All	8.5
NP	General-purpose soda-lime glass	Powdered Glass	All	5.0

- a The description applies to containers of this type of glass usually available.
 b Size indicates the overflow capacity of the container.

7. POWDERED GLASS TEST

Rinse thoroughly with Purified Water 6 or more containers selected at random, and dry them with a current of clean, dry air. Crush the containers into fragments about 25 mm in size, divide about 100 g of the coarsely crushed glass into three approximately equal portions, and place one of the portions in the special mortar. With the pestle in place, crush the glass further by striking 3 or 4 blows with the hammer. Nest the sieves, and empty the mortar into the No. 20 sieve. Repeat the operation on each of the two remaining portions of glass, emptying the mortar each time into the No. 20 sieve. Shake the sieves for a short time, then remove the glass from the Nos.20 and 40 sieves, and again crush and sieve as before. Repeat again this crushing and sieving operation. Empty the receiving pan, reassemble the nest of sieves, and shake by mechanical means for 5 minutes or by hand for an equivalent length of time. Transfer the portion retained on the No. 50 sieve, which should weigh in excess of 10 g, to a closed container, and store in a desiccator until used for the test.

Spread the specimen on a piece of glazed paper, and pass a magnet through it to remove particles of iron that may be introduced during the crushing. Transfer the specimen to a 250-mL conical flask of resistant glass, and wash it with six 30-mL portions of acetone, swirling each time for about 30 seconds and carefully decanting the acetone. After washing, the specimen should be free from agglomerations of glass powder, and the surface of the grains should be practically free from adhering fine particles. Dry the flask and contents for 20 minutes at 140°, transfer the grains to a weighing bottle, and cool in a desiccator. Use the test specimen within 48 hours after drying.

7.1 Procedure

Transfer 10.0 g of the prepared specimen, accurately weighed, to a 250-mL conical flask that has been digested (aged) previously with High-Purity Water in a bath at 90° for at least 24 hours or at 121° for 1 hour. Add 50 ml of High-Purity Water to this flask and to one similarly prepared to provide a blank. Cap all flasks with borosilicate glass beakers that previously have been treated as described for the flasks and that are of such size that the bottoms of the beakers fit snugly down on the top rims of the containers. Place the containers in the autoclave, and close it securely, leaving the vent cock open. Heat until steam issues vigorously from the vent cock, and continue heating for 10 minutes. Close the vent cock, and adjust the temperature to 121°, taking 19 to 23 minutes to reach the desired temperature. Hold the temperature at 121 ± 2.0° for 30 minutes, counting from the time this temperature is reached. Reduce the heat so that the autoclave cools and comes to atmospheric pressure in 38 to 46 minutes, being vented as necessary to prevent the formation of a vacuum. Cool the flask at once in running water, Decant the water from the flask into a suitably cleansed vessel, and wash the residual powdered glass with four 15-mL portions of High-Purity Water, adding the decanted washings to the main portion. Add 5

drops of Methyl Red Solution, and titrate immediately with 0.020 N sulfuric acid. If the volume of titrating solution is expected to be less than 10 ml, use a microburet. Record the volume of 0.020 N sulfuric acid used to neutralize the extract from 10 g of the prepared specimen of glass, corrected for a blank. The volume does not exceed that indicated in Table 2 for the type of glass concerned.

8. WATER ATTACK AT 121°

Rinse thoroughly 3 or more containers, selected at random, twice with High-Purity Water.

8.1 Procedure

Fill each container to 90% of its overflow capacity with High-Purity Water, and proceed as directed for Procedure under Powdered Glass Test, beginning with “Cap all flasks,” except that the time of autoclaving shall be 60 minutes instead of 30 minutes, and ending with “to prevent the formation of a vacuum.” Empty the contents from 1 or more containers into a 100-mL graduated cylinder, combining, in the case of smaller containers, the contents of several containers to obtain a volume of 100 ml. Place the pooled specimen in a 250-mL conical flask of resistant glass, add 5 drops of Methyl Red Solution, and titrate, while warm, with 0.020 N sulfuric acid. Complete the titration within 60 minutes after opening the autoclave. Record the volume of 0.020 N sulfuric acid used, corrected for a blank obtained by titrating 100 ml of High-Purity Water at the same temperature and with the same amount of indicator. The volume does not exceed that indicated in Table 2 for the type of glass concerned.

Arsenic

Use as the Test Preparation 35 ml of the water from one Type I glass container or, in the case of smaller containers, 35 ml of the combined contents of several Type I glass containers, prepared as directed for Procedure under Water Attack at 121 °: the limit is 0.1 mg per g

9. QUALITY RECORD(s)/FORM(s)

The following Quality Records shall be generated and managed in accordance with the Procedure for Control of Company Quality Records (4.12).

Form Reference No.	
Certificate of analysis	IR/QC/PMC/010