

HAND PACKAGED ORS FOR DIARRHOEA

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ABSTRACT

The feasibility of a simple method for the preparation of Oral Rehydration Solution (ORS) packets suitable for a cottage industry was tried out. Contents of the packet contained ingredients to make one litre of ORS according to formula approved by WHO excepting that glucose was replaced by common sugar (sucrose). Salts and sugar measured for 200 packets were mixed thoroughly in a bowl. A standardized scoop was used to measure the salt-mixture for one litre of ORS and packed in polythelene bags. Trained housewives prepared the packets. A printed leaflet containing the composition and instructions for making the solution and administration of ORS was wrapped around each packet. Every step of the preparation of the packets was controlled.

For quality control, 3 to 5 packets were tested for weight and electrolyte contents from each lot of 200 ORS packets. The results were found to be satisfactory. The shelf life of the ORS packets in different seasons and in various conditions of temperature and humidity was also tested. Some physical changes were observed; but composition remained almost constant upto 8 months of storage. A simple method for quality control was developed by estimating chloride by simple titrimetric analysis. A good correlation was found between Na^+ and Cl^- ions in ORS.

INTRODUCTION

The efficacy of oral rehydration solution (ORS) in the treatment of diarrhoeal diseases has been accepted worldwide¹⁻². But when ORS is packaged centrally there is a tremendous amount of logistics involved in distributing this throughout the country. This problem is especially faced by rural areas of developing countries, and this is where ORS is most needed because of predominance of diarrhoea. The logistics and supply problems may result in scarcity and thereby unnaturally pushing the prices up.

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Another alternative is to use either the pinch and scoop method or the double-ended spoon and make ORS at home. But field trials have shown that even though rural women with no education can make ORS satisfactorily, repeated training by a trained person is essential. This is not practical for all the areas where diarrhoea is endemic. To overcome this disadvantage a simple method, suitable as a cottage industry for the preparation of safe oral-rehydration salt packets was developed. All ingredients were tested in the Biochemistry laboratory of ICDDR,B; the ORS formula recommended by WHO was followed except 20 gm glucose was substituted by 40 gm sucrose. Ingredients for preparing 200 packets, each for 1 litre ORS, were measured in a balance and mixed thoroughly in a bowl. For testing the homogeneity of the mixture of salts and sugar, 3 samples each containing 47.5 gms. of the mixture (which is required for making 1 litre ORS) were taken from bowl and assayed separately. When the results were found to be within the satisfactory range the salt-sugar mixture was then packed. It was found that 30 minutes of continuous mixing by hand was needed for making a homogenous mixture. Sometimes sodium bicarbonate had to be ground by hand and sieved for proper mixing. A standardized plastic scoop measuring 47.5 gms. was used to measure mixture for making one litre packets. The scoop was made in this laboratory by cutting a 50 ml plastic measuring cylinder to hold exactly 47.5 gms. of the mixture. The measured mixture was then sealed in a polythelene bag by an electric sealer or a candle. Housewives were instructed to prepare packets and mastered the technique very well within three months. A leaflet describing the composition and instructions on making the solution and for administering it was wrapped around the packets.

From each lot of 200 packets 3 to 5 bags were tested for quality by measuring the gross weight and electrolytes contents. Electrolytes were estimated in the Biochemistry laboratory of ICDDR,B using IL analyser. A total of 3359 samples were analyzed and the results were tabulated. The mean net weight of the packets tested was 48.2 gms. with S.D. $\pm$ 0.35. The optimum weight of the mixture for 1 litre ORS is 47.5 gm. The mean weight of polythelene bags was 1.4 gm.

The shelf life of the ORS packets was also tested. Sixty packets prepared in May 1980 were kept exposed to the atmosphere for eight months and analysed. It was found that the glucose, HCO_3^- , pH and moisture content varied during the period of storage. Physical changes noticed were: colour, changed from white to brown and formed soft lump. But the lump did not effect solubility of the mixture. CO_2 came down from 29.6 to 23.7 mmol/l, glucose from 107 to 100 mmol/l, pH increased from 8.4 to 9.1 and 1.3% moisture was absorbed by those packets during the eight months of storage. The bicarbonate content of the salt mixture decreased gradually during storage, packets that are usually stored from 3-5 months were safe and contained optimum concentration⁷ of bicarbonate to treat diarrhoea. In the

rainy season those packets were also analysed after one month and 3 months. Except moisture content all other components remained stable. The mean moisture content was 5% and varied from 2.6 - 10.5% during 3 months of storage. During the rainy season in Bangladesh humidity varies from 98 - 100% and temperature from 28° - 30°C. When the rainy season was over, water absorbed, diffused out of the packets because the polythelene bags were semipermeable to water.

The concentration of Na^+ ion in the ORS is considered to be the most critical item for its safety and efficacy (14-15). Estimation of sodium requires the use of a flame photometer which is expensive and requires a high level technical competence for operation and maintenance and is not suitable for quality control in rural areas. We evaluated an indirect method for the estimation of sodium in ORS solution by titrating chloride against silver nitrate in presence of an indicator¹⁶.

The modified Mohr method was used to titrate chloride in oral solution. The chloride in neutral or weak alkaline solution containing chromates is titrated with silver nitrate. Silver chloride precipitates and at the end point red silver chromate is formed. Oral therapy solution is weakly alkaline, therefore adjustment of alkalinity or neutrality of the solution was not necessary. This method is ideal to titrate chloride in oral therapy solution because the interfering substances iodine, bromide, phosphate, sulfide and cyanide are not likely to be present in ORS in important amounts.

- Reagents:
- (a) Standard AgNO_3 solution (0.01 N): 1.699 gm AgNO_3 was dissolved in 1000 ml. volumetric flask and the volume was adjusted up to the mark.
 - (b) Standard NaCl solution (0.01 N): 0.5845 gm of reagent grade NaCl was dissolved in 1000 ml. volumetric flask and volume was made up to the mark. This solution is used to standardize silver nitrate solution.
 - (c) Potassium chromate indicator solution: 50 gm of K_2CrO_4 was dissolved in about 700 ml of distilled water and to this solution silver nitrate solution was added to produce a slight red precipitation. After keeping undisturbed overnight the solution was filtered and diluted to one litre.

Procedure:

To 1 ml of oral therapy solution in an 100 ml Erleenmeyer flask about 20 ml of water was added. The solution was warmed slightly on a heater or a spirit lamp and then 0.5 ml of K_2CrO_4 solution was added to it. The titration was carried out against standard AgNO_3 solution from burette until a colour change from pure yellow to pinkish yellow, coloured precipitation appeared. The indicator blank should be

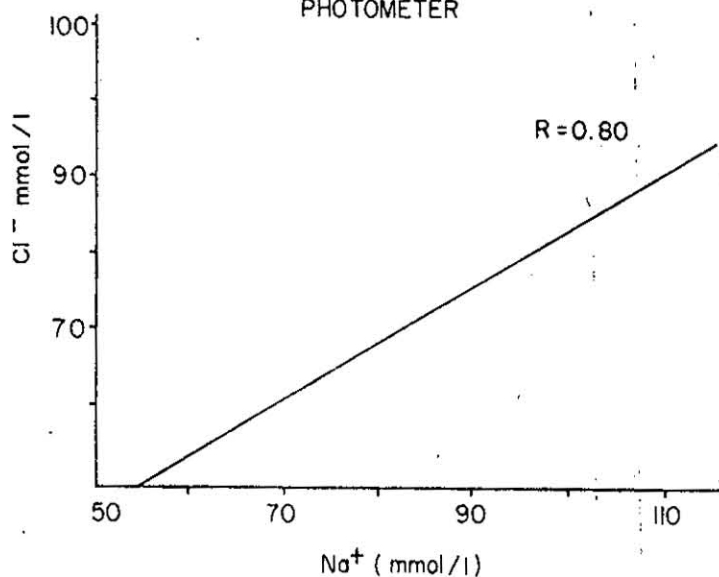
determined by titrating water in the same way. One standard should be run in each lot of analysis.

calculation $X = V \times S \times 1000 = \text{Cl}^- \text{ in mmol/l of ORS.}$
 Where, X = Chloride concentration in ORS in mmol/l.
 V = Vol. of AgNO_3 used to titrate the solution.
 S = the actual strength in normality of AgNO_3 .

The chloride values obtained by the automatic chloride counter and by the manual titrimetric method correlate strongly. The correlation coefficient was found to be 0.98. The correlation coefficient between chloride values measured by the titrimetric method and Na values measured by flame photometry was found to be 0.8 (Figure 1).

Fig. 1

CORRELATION BETWEEN CHLORIDE CONC.
 ESTIMATED BY TITRIMETRIC METHOD AND
 SODIUM CONC. ESTIMATED BY FLAME
 PHOTOMETER



It may be concluded that if centrally tested ingredients are supplied, cottage industry for making ORS packets may be set up and housewives can be trained to make safe oral rehydration packets. The simple titrimetric method not requiring sophisticated instruments and adaptable to simple field use has been found to provide an accurate estimation of chloride and therefore can

be used to estimate sodium for ensuring the safety of oral rehydration salt packets. The estimation of chloride requires glass ware and reagents which are easily available in Bangladesh. Centrally prepared and standardized reagents may be supplied. To simplify the preparation of ORS packets sodium-bicarbonate was mixed with other ingredients. Results show that even when the packets are exposed to normal conditions of temperature and humidity for upto eight months, those packets could be safely used for rehydration. However, as a safety measure, it is recommended that packets should be used by three months of preparation. Another advantage of mixing ingredients for 200 packets at a time was that the large quantity was easier to measure and reduced the margin of error incurred by using a rough balance.

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