

Production of Zinc Tablets and Zinc Oral Solutions

Guidelines for Programme Managers and Pharmaceutical Manufacturers

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Definitions

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| Dehydration | Loss of water and dissolved salts from the body, occurring, for instance, as a result of diarrhoea. |
| Rehydration | The correction of dehydration. |
| Oral Rehydration Therapy (ORT) | The administration of fluid by mouth to prevent or correct the dehydration that is a consequence of diarrhoea. |
| Oral Rehydration Salt (ORS) solution | Specifically, the complete, new WHO/UNICEF formula. |

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Introduction

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WHO and UNICEF have released revised recommendations for the management of diarrhoea aimed at dramatically reducing the number of deaths due to diarrhoea. These new recommendations take into account two significant recent advances: demonstration of the increased efficacy of a new formulation for ORS containing lower concentrations of glucose and salt, and success in using zinc supplementation in addition to rehydration therapy in the management of diarrhoeal diseases¹.

In order to ensure that these recommendations become effective, it is essential that the industry be encouraged to prepare zinc formulations which contain only zinc as active ingredient. Many vitamin products and other nutritional supplements containing zinc are available commercially. However, it is uncommon for these products to have the recommended dosage of zinc. Therefore a product containing only zinc is required. The product should be formulated in such a way as to mask the strong metallic aftertaste of zinc to enhance acceptability to children. Zinc salt formulations for administration to children could take the form of oral solution or tablets. The specifications of zinc products for use in the management of diarrhoea are listed in Annex 1.

For all organizations involved in the procurement of zinc tablets or zinc oral solutions, the procurement should be made from trusted sources, such as those companies pre-qualified for zinc tablets and oral solutions in the UNICEF suppliers list and those with a proven record of quality products. When organizations make a tender to purchase zinc products, the tender should clearly

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