

# PRODUCT SPECIFICATION SHEET

Ascorbic acid (Vitamin C) 250mg Tab PAC or BLIS 1000 Material Nr.: S1580006 Version no: 1.0 Author: ARF Reviewed by: DK, MCR Date: 25.11.2022

### **1. General Description**

Vitamin C as Ascorbic acid 250mg tablets in a blister (e.g., 10x100) or bottle pack of 1000 tablets. The tablets may be swallowable or chewable.

### 2. Technical Specifications

Ascorbic acid 250 mg tablets, pack of 1000 tablets, complying with one of the pharmacopeias listed below.

### 3. Contaminants

Preferably meets the EMA requirements for contaminants. Preferably does not contain Thiourea and polyvinyl Pyrrolidone.

#### 4. Acceptable Pharmacopeias

Should comply with one of the below listed pharmacopeias

British Pharmacopoeia (BP) United States Pharmacopoeia (USP) European Pharmacopoeia (Ph.Eur) International Pharmacopoeia (Ph.Int)

# 5. Dispensing instructions

Dispense in original packaging. Do not repack.

# 6. Shelf life

36 months preferred. Minimum shelf-life requirement is 24 months.

#### 7. Storage and transportation

Do not store above 30°C. Protect from light and moisture. Keep out of the reach and sight of children. The manufacturer must specify storage and transport temperature and related conditions on product label and all subsequent packaging.

#### 8. Packaging and Labelling

As per UNICEF Technical requirements. See UNICEF Technical requirements for more detailed information. <u>5 (unicef.org)</u>

**Language Text:** All the packaging material, including label and patient information leaflet, must be in English & French, preferably in English French & Arabic text.

# **Useful Resources**

- 1. Minimum stability testing reporting requirements (guidance) for stability reports- Nutritional supplements (Tablets & oral solutions)
- 2. Interagency finished pharmaceutical product questionnaire
- 3. Technical questionnaire for pharmaceutical manufacturers
- 4. Technical Requirements for Pharmaceutical and Nutrition Products

# FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies <a>[sd.nutritionsupplies@unicef.org]</a>

Technical resources for nutrition products | UNICEF Supply Division