



# HPECT500 Tablets Specification

Issue Date: 12/06/2022

**PRODUCT:** New-Gar® High Potency Enteric Coated white Garlic tablets 500MG  
**PRODUCT CODE No.:**HPECT500      **Technical Director:** Mary Gabriel

*Complies with all current USP/NF*

**Garlic source:** China

**Mfg Source:** USA

**Tablets made with high potency New-Gar® standardized & deodorized garlic granules**

Item	Specification	Method of Analysis
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<b>Appearance:</b>	medium oblong white tablets	Visual
<b>Identity :</b>	Garlic, Allium sativum species	DNA Species ID, SOP 17236
<b>Taste /Odor :</b>	none due to enteric coating	

**Active Ingredients**

<b>Allicin Potential*</b>	Min.5,000 ppm	C-18 HPLC/ALC118A
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**Disintegration and Dissolution:**

Enteric coating remains intact for 60 min in gastric fluids , and disintegrates with an additional 60 min in the intestinal fluids. NSP 1.30 method meeting USP method 724A

**Weight variation :** USP Vol23 , Target 1380mg, Range : 1300-1390mg (97-102%)

**Thickness :** 0.26-0.29 inches , **Hardness :** 7.5Kp

**Heavy metals / Must Meet USP Limits <10mg/kg**      **USP method 231**

<b>Arsenic</b>	< 0.50mg/kg	ICP/MS
<b>Cadmium</b>	< 0.50mg/kg	AICP05A
<b>Lead</b>	< 0.20mg/kg	ICP/MS
<b>Mercury</b>	< 0.50mg/kg	ICP/MS

**Microbiological (Same as USP<2021,2022>)**

<b>Total plate Count</b>	<10,000 cfu/g	AOAC 966.23
<b>Yeast and Mold</b>	<100 cfu/g	FDA-BAM 7 <sup>th</sup> ed.
<b>Coliforms</b>	<20 cfu/g	AOAC 966.23
<b>E.Coli</b>	negative	AOAC 966.23
<b>Pseudomonas</b>	negative	AOAC /BAM
<b>Salmonella</b>	negative	AOAC /BAM
<b>Staph Aureus</b>	negative	AOAC /BAM

**Actives Testing :** \*Each batch is tested for Allicin potential

**Batch record examination must be conducted by Quality personnel and batch would be released in compliance with the requirements set forth in 21 CFR 111**

**Active Ingredient:** 500 mg of high Allicin New-Gar® garlic

**Other Ingredients:** calcium phosphate ,stearic acid, silicon dioxide , magnesium stearate, croscarmellose sodium, & enteric coating: cellulose & methacrylate.

**Pesticides meet all regulations**

- Garlic was not sterilized neither by ETO treatment , nor by irradiation. Only dry heat sterilization. Garlic in non -GMO

**Storage Conditions & shelf life:** Store in a cool, dry place, do not freeze. Shelf life is 3yrs.