

## Pharmaceutical Grade CMC

### Introduction

Fortune Biotech CMC is a multifunctional pharmaceutical excipient widely used in drug formulations due to its safety, stability, and unique physical-chemical properties. Acts as a binder, disintegrant, thickener, suspending agent, and sustained-release matrix.

### Application

- Binds powder into solid tablets.
- Helps tablets break down quickly in water for better absorption.
- Thickens liquid medicines to prevent settling.
- Controls slow drug release for longer-lasting effects.
- Aids manufacturing and masks taste.
- Used in gels and ointments for easy application.

### Function

- Thickening
- Binding
- Disintegration
- Sustained Release
- Lubrication & Coating
- Topical Base

### Package

25kg per multi -layer kraft paper bag with PE inner bag. Package can be customized as required. Once open it, please use up ASAP.

### Storage & Shelf Life

Store in a cool, dry, and ventilated place within a well-sealed container. Shelf life is 24 months. However, as a result of natural degradation process the viscosity of CMC may decrease in time. Therefore, after 12 months from date of manufacturing, the product can still be used safely up to the indicated expiry date, but may need a slight dosage correction in order to give optimum performance in the application.

**Main Specification****(Complies with requirements of USP-NF, EP, ChP)**

<b>Physical &amp; Chemical Parameters</b>		
Description	White to off-white free flow powder, hygroscopic after drying	
Identification	A. No precipitate is formed. B. A blue, cotton-like precipitate is formed. C. Color reaction: Bright yellow flame is formed.	
Model & Viscosity	PHAL6	1% 20-50cps
	PHAH6	1% 200-500cps
	PHA1000	1% 1000-2000cps
	PHA2000	1% 2000-3000cps
	PHA5000	1% 5000-6000cps
Degree of substitution	0.75-0.9	
Purity	≥99.5%	
Sodium glycolate	≤0.4%	
Sodium chloride	≤0.5%	
pH	6.0 - 8.5	
Sodium content	≤12.4%	
Loss on drying	≤8%	
Sulphated ash	20.0%-33.3%	
Residual solvent	Absent	
<b>Heavy Metals Parameters</b>		
Heavy metals	≤10ppm	
Lead (as Pb)	≤2ppm	
Arsenic (As)	≤2ppm	
Mercury (Hg)	≤1ppm	

Cadmium (Cd)	≤1ppm
<b>Microbiological Parameters</b>	
Total plate count	≤500cfu/g
Mould & yeasts	≤100cfu/g
E.coli	Absent
Salmonella (cfu/25g)	Absent
Staphylococcus aureus (cfu/25g)	Absent

Note: Products with different viscosities, degrees of substitution, and particle sizes can be customized according to the specific requirements of customers.

Fortune Biotech CMC has been found to comply with the requirements of International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969 (Rev.2020) and obtains GMP Verification of Conformity.

### Fortune Biotech

North of Shengfa Road  
 Zhanghuang Town Industrial Park  
 Yutai County, Jining, Shandong  
 Province, China  
 Postal Code: 272350  
 Tel: +86-0537-6106347  
 Fax: +86-0537-6176789  
 Email: sales@sdfrcchem.com