Certificate Of Analysis

Item Number	C1477	Lot Number	2JE0335
Item	Carbomer 940, NF		
CAS Number	9003-01-4		
Molecular Formula		Molecular Weight	M.W.

Test	Specification		Result
	min	max	
CARBOXYLIC ACID GROUPS (DRIED BASIS)	56.0	68.0%	60.4 %
VISCOSITY OF A 0.5% SOLUTION	40,000	60,000 mPa·s	52,000
LOSS ON DRYING		2.0%	0.2 %
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT
BENZENE		0.5%	0.0568 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			21-FEB-2022
DATE OF MANUFACTURE			22-FEB-2020
APPEARANCE			WHITE FLUFFY POWDER
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ

Certificate of Analysis Results Certified by:

Himanshu Patel
Quality Control Manager
Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.