

Excipients

NISSO HPC

Hydroxypropyl Cellulose

TECHNICAL DATA SHEET

HPC GRADES & APPLICATIONS

NISSO HPC		SSL	SL	L	LM	LMM	M	H	VH
Viscosity (mPa·s) 20°C/2% aq. solution		2.0-2.9	3.0-5.9	6.0-10.0	11-20	21-50	150-400	1,000-4,000	4,001-6,000
Molecular Weight/ GPC Method		40,000	100,000	140,000	180,000	280,000	700,000	1,000,000	2,500,000
AVAILABILITY	Regular Powder (40 mesh) *D₅₀: 150-190 μm	✓*	✓	✓	✓	✓	✓	✓	✓
	Fine Powder (100 mesh) *D₅₀: 80-110 μm		✓	✓			✓	✓	✓#
	Super Fine Powder (330 mesh) *D₅₀: 20 μm	✓							
APPLICATION	High Shear Granulation ★★💧	████████████████████							
	Fluidized Bed Granulation 💧	████████████████████████████████████████							
	Direct Compression Dry Granulation ★★	████████████████████							
	Hot Melt Processing ★★💧	████████████████████████████████████████████████████████████████████████████████							
	Film Coating 💧	████████████████████████████████████████							
	Solubility Enhancement ★★💧	████████████████							
	Controlled Release Matrix Tablets ★★💧							████████████████████████████████████████	

* Particle size of the Regular Powder: 85 μm # VH Fine Powder: Under development

★★ = Dry / Powder Use 💧 = Wet / Solution Use



NIPPON SODA CO., LTD.

Powder Types, Uses and Advantages

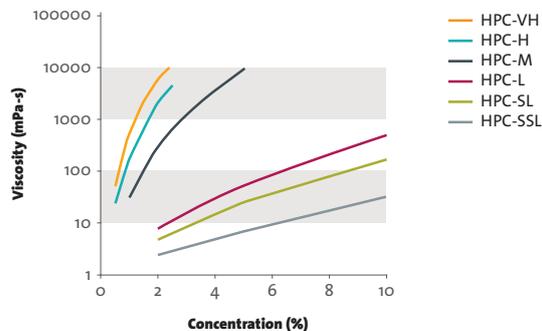
Regular Powder: Regular Powder (RP) type HPC is mainly used in solution form. As a binder for wet granulation applications, low viscosity grades of HPC give an excellent balance of properties to oral solid dosage tablets by imparting superior strength and elegance without compromise of the disintegration profile. As a film coating agent, HPC improves film flexibility, elongation, and adhesion to the tablet.

Fine Powder: Fine Powder (FP) type HPC has better formability than Regular Powder type and is mainly used in dry powder form. Having good wettability, lower viscosity grades are used as a dry-mix binder in high shear mixer formulations. Higher viscosity grades of HPC are applicable to controlled release matrix tablet formulations by direct compression application and give better release profiles compared to other common CR polymers.

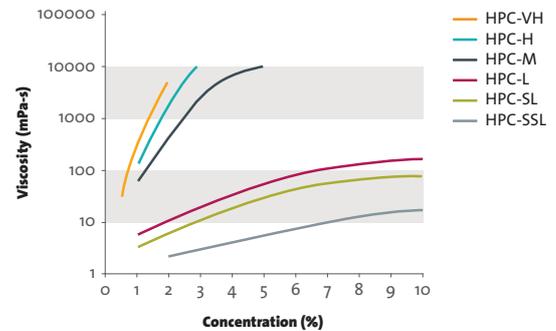
Super Fine Powder: Super Fine Powder (SFP) type offers the highest level of formability. Excellent tablet properties can be obtained at low use level in direct compression applications. SFP is applicable to poorly compressible drug and high drug load formulations. Additionally, excellent tablet properties can be achieved in orally disintegration tablet (ODT) formulations by direct compression method when SFP grade is used in combination with a super disintegrator.

NISSO HPC Viscosity Change by Temperature, Concentration

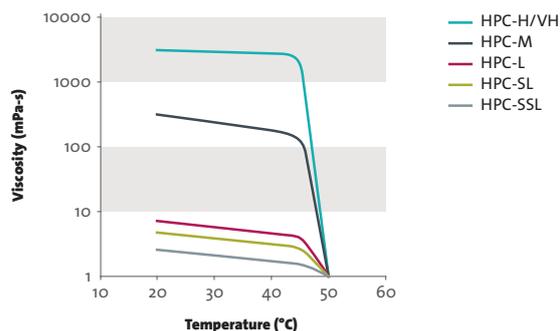
Viscosity Change vs. Concentration, aqueous solution



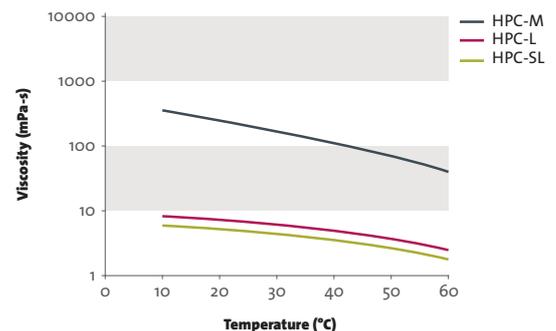
Viscosity Change vs. Concentration, ethanol solution



Viscosity Change vs. Temperature, aqueous solution



Viscosity Change vs. Temperature, ethanol solution



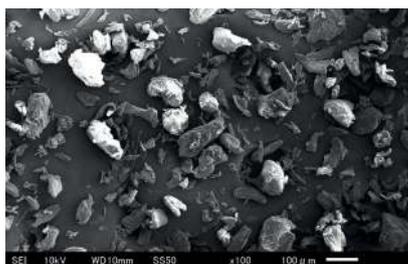
NISSO HPC Powder Characteristics

NISSO HPC Particle Size Distribution

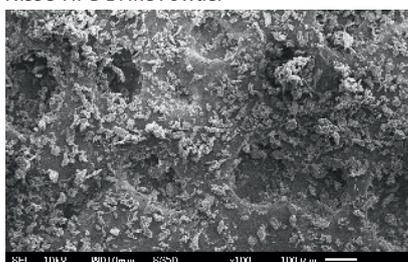
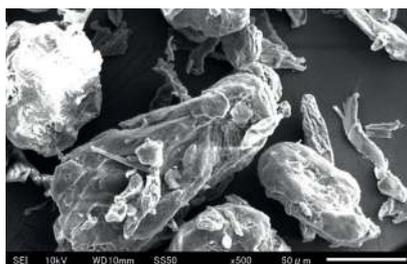
	D10 (µm)	D50 (µm)	D90 (µm)
HPC-SSL	30	85	185
HPC-SL	65	155	275
HPC-L	75	160	355
HPC-M	80	185	355
HPC-H	85	185	365
HPC-VH	85	185	365
FP GRADES	35-50	80-110	150-200
SFP GRADE	8	20	50

NISSO HPC Particle Shape

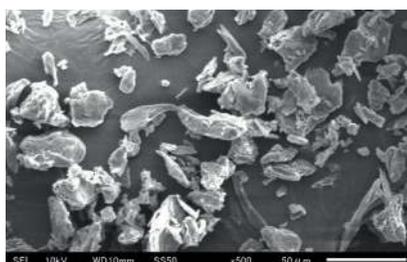
Roundish particle shape gives better flowability. NISSO HPC has no added flow agents.



NISSO HPC-L Fine Powder



NISSO HPC-SSL Super Fine Powder



NISSO HPC for Pharmaceutical Applications

Application	Recommended Grade
WET GRANULATION (DISSOLVED BINDER)	SSL, SL, L
WET GRANULATION (DRY BINDER ADDITION)	SSL SFP, SL FP, L FP
DIRECT COMPRESSION	SSL SFP, SL FP, L FP
CONTROLLED RELEASE MATRIX	M/M FP, H/H FP, VH/VH FP
FILM COATING	SSL, SL, L, LM
SOLUBILITY ENHANCEMENT	SSL, SL
ORAL LIQUIDS	LM, LMM, M, H, VH
TOPICAL APPLICATIONS	LM, LMM, M, H, VH

Additional Information

Chemical Structure CAS No.	HYDROXYPROPYL CELLULOSE 9004-64-2 <div style="text-align: center;"> <p>R: -H or $\left(\text{-CH}_2\text{-}\overset{\text{CH}_3}{\text{CH}}\text{-O-} \right)_m$</p> </div>
Safety	HAZARDOUS IDENTIFICATION, FIRST AID MEASURES AND FIRE FIGHTING MEASURES: SEE MSDS ACCIDENTAL RELEASE MEASURES: SWEEP UP, PLACE IN CONTAINERS AND HOLD FOR WASTE DISPOSAL STABILITY/REACTIVITY: - FLASH POINT: NOT APPLICABLE - POWDER EXPLOSIVENESS: 65G/M ³ (REGULAR POWDER); 50G/M ³ (FINE POWDER, SUPER FINE POWDER) (LOWER LIMIT) - HPC IS CHEMICALLY STABLE BUT MUST BE KEPT AWAY FROM STRONG OXIDIZING AGENTS
Compendial Status	USP/NF, EP, JP COMPLIANT; FOOD USE APPROVED 21 CFR 172.870, E463
Additives	NISSO HPC CONTAINS NO SILICA OR OTHER ADDITIVES
Expiration	EXPIRATION DATE IS FIVE (5) YEARS FROM DATE OF MANUFACTURE, * HPC-VH/VH FP GRADE IS ONE (1) YEAR FROM DATE OF MANUFACTURE
Packaging	10 KG BOX, DOUBLE LINED PE BAG
Site of Manufacture	NIPPON SODA CO., LTD. NIHONGI PLANT 950 FUJISAWA, JOETSU CITY NIIGATA PREFECTURE, JAPAN

NOTICE

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