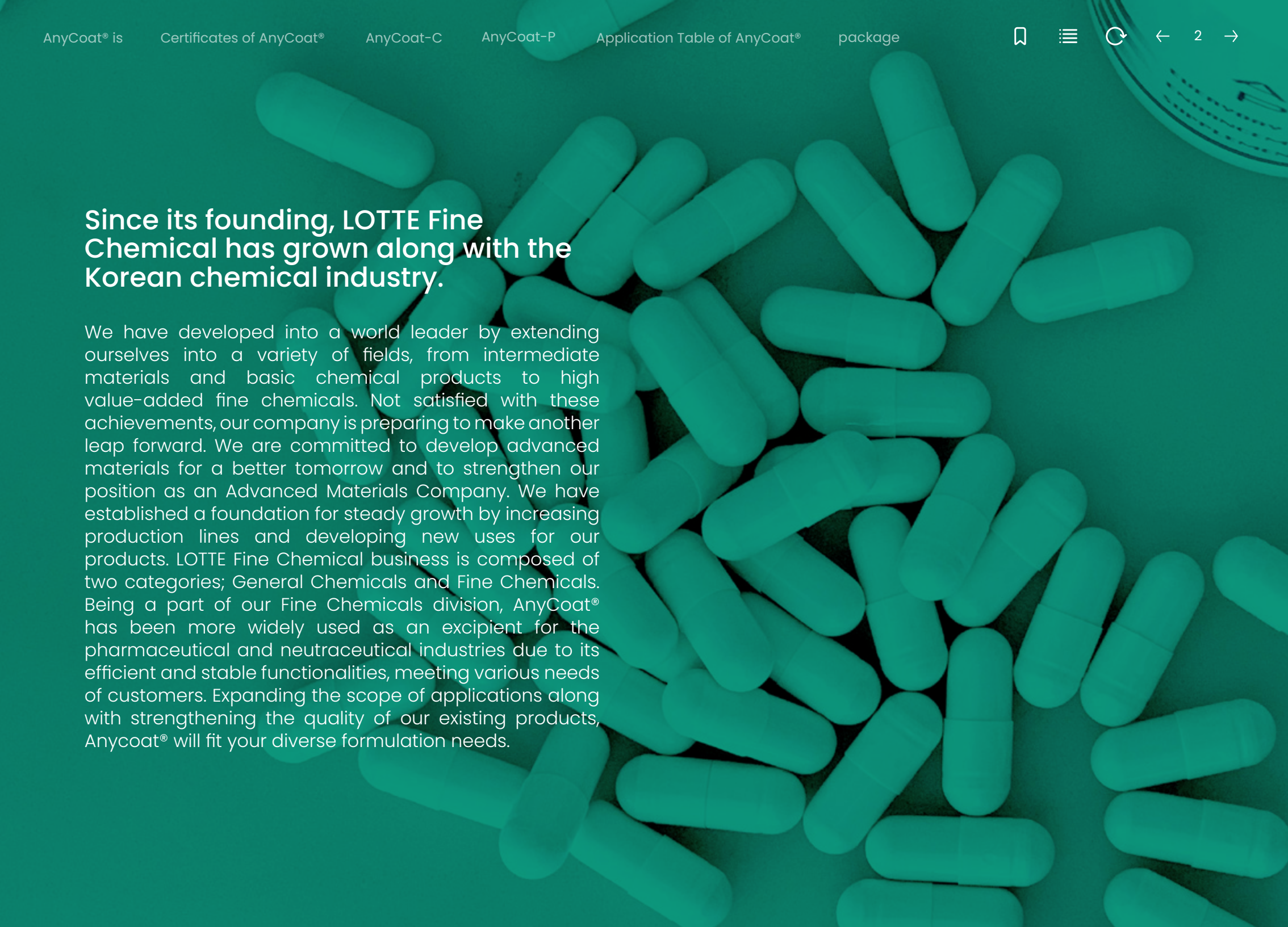
FROM NATURE, BESIDE YOU

AnyCoat®

LOTTE FINE CHEMICAL
www.lotte-cellulose.com



Since its founding, LOTTE Fine Chemical has grown along with the Korean chemical industry.

We have developed into a world leader by extending ourselves into a variety of fields, from intermediate materials and basic chemical products to high value-added fine chemicals. Not satisfied with these achievements, our company is preparing to make another leap forward. We are committed to develop advanced materials for a better tomorrow and to strengthen our position as an Advanced Materials Company. We have established a foundation for steady growth by increasing production lines and developing new uses for our products. LOTTE Fine Chemical business is composed of two categories; General Chemicals and Fine Chemicals. Being a part of our Fine Chemicals division, AnyCoat® has been more widely used as an excipient for the pharmaceutical and neutraceutical industries due to its efficient and stable functionalities, meeting various needs of customers. Expanding the scope of applications along with strengthening the quality of our existing products, Anycoat® will fit your diverse formulation needs.

Contents

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AnyCoat® Is

AnyCoat® is a brand name of the cellulose ether for the pharmaceuticals and neutraceuticals manufactured by LOTTE Fine Chemical.
AnyCoat-C is Hypromellose (Hydroxypropylmethylcellulose)
and AnyCoat-P is Hypromellose Phthalate (Hydroxypropylmethylcellulose phthalate).
AnyCoat® is compliant with USP/NF, EP, JP, KP, and etc.
Besides, AnyCoat® has certificates of Kosher, ISO, DMF issued from US FDA,
and CEP(COS) issued from EDQM.

AnyCoat-C comes in diverse viscosity ranges from 3 to 100,000 mPa·s, and it can be widely used for the tablet coating, granulation, binder, thickener, stabilizer and making vegetable capsule.

AnyCoat-P can be widely used for the enteric coating agent to shield APIs against the degradation by gastric acid or keeping them from bringing about side effects in the stomach.

Certificates of AnyCoat®

Certificate	Agency	Remarks
Approval of medicine manufacturing	MFDS[1)]	1) Korea Ministry of Food and Drug Safety
Kosher	Orthodox Union	
ISO 9001	KGS[2)]	2) Korea Gas Safety Corporation
DMF[3)]	US FDA, NMPA[4)]	3) Drug Master File 4) China National Medical Products Administration
CEP(COS)[5)]	EDQM	5) Certificate of Suitability to the Monographs of the European Pharmacopeia
HALAL	KMF[6)]	6) Korea Muslim Federation

Other Certificates and Statements of AnyCoat®

- TSE/BSE statement
- Non-GMO statement
- Allergen statement
- Residual pesticide statement
- Residual solvent statement
- Impurity profile statement

AnyCoat-C

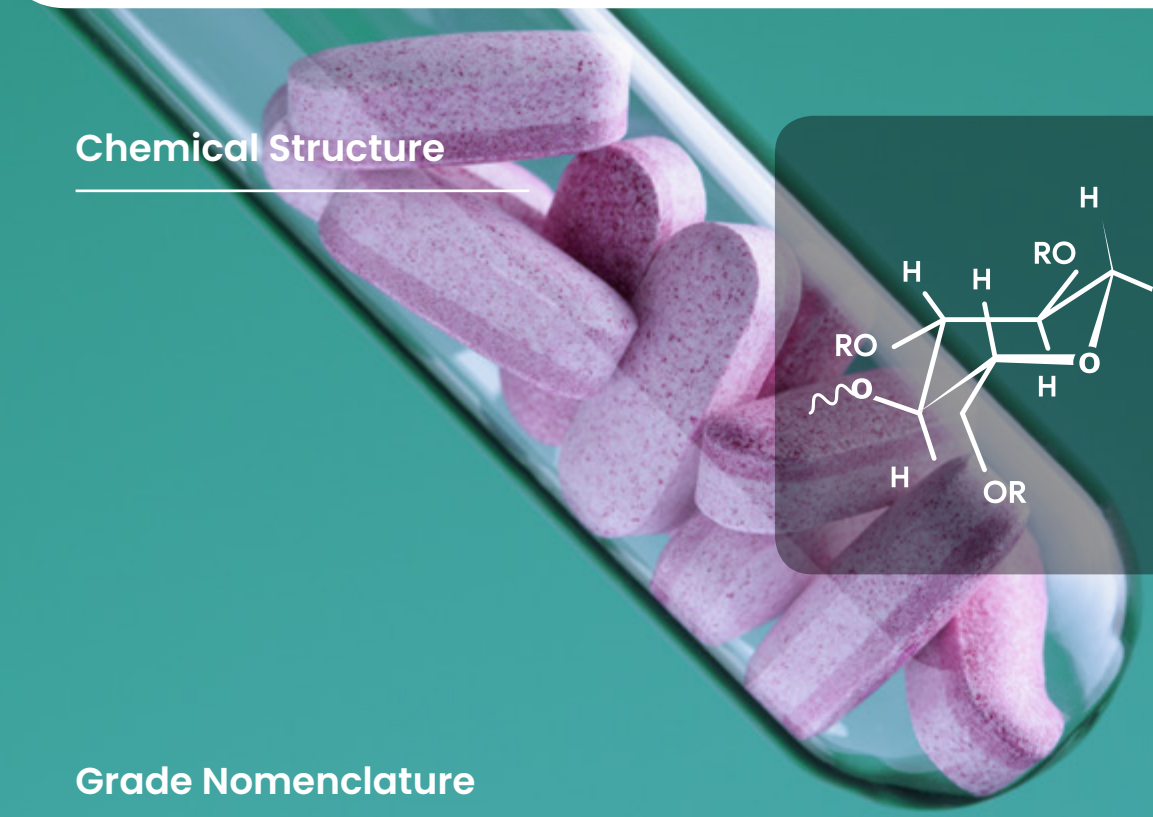
General Characteristics

CAS number	9004-65-3
Chemical name	Cellulose, 2-hydroxypropyl methyl ether
Generic name	Hypromellose, Hydroxypropylmethylcellulose
Molecular weight	10,000 ~ 1,000,000
Gelling temperature	40 ~ 90˚C
Auto-ignition point	330˚C
Bulk density	0.30 ~ 0.52 g/ml
Angle of repose	35 ~ 44°
Admission to compendium	USP/NF, EP, JP, KP, CODEX, JECFA, FCC, etc

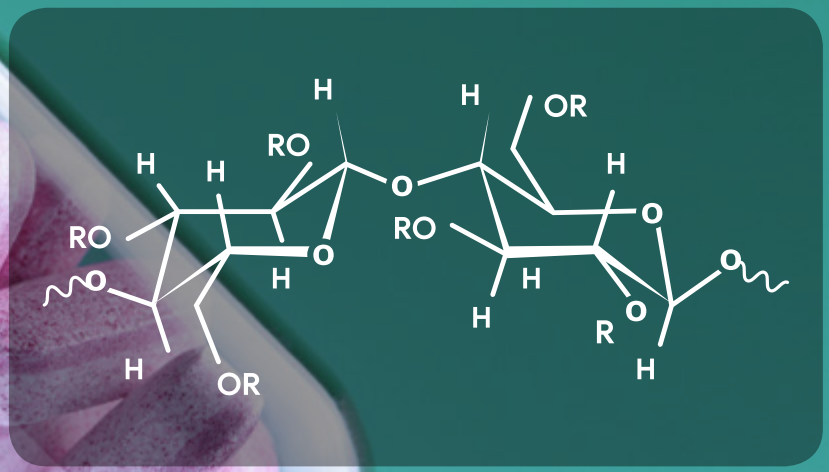
Specifications

Test	USP-NF 2021	EP10	JP18
Identification	+	+	+
Characters		+	
Appearance of solution		+	
pH (2% w/w solution)	5.0 ~ 8.0	5.0 ~ 8.0	5.0 ~ 8.0
Apparent viscosity			
< 600mPa·s	80 ~ 120% of the normal value	80 ~ 120% of the normal value	80 ~ 120% of the normal value
≥ 600mPa·s	75 ~ 140% of the normal value	75 ~ 140% of the normal value	75 ~ 140% of the normal value
Loss on drying	≤ 5.0%	≤ 5.0%	≤ 5.0%
Residue on ignition	≤ 1.5%	≤ 1.5% (sulfated ash)	≤ 1.5%
Heavy metals	-	-	≤ 20ppm
Methoxy content			
Type 2208	19.0 ~ 24.0%	19.0 ~ 24.0%	19.0 ~ 24.0%
Type 2906	27.0 ~ 30.0%	27.0 ~ 30.0%	27.0 ~ 30.0%
Type 2910	28.0 ~ 30.0%	28.0 ~ 30.0%	28.0 ~ 30.0%
Hydroxypropoxy content			
Type 2208	4.0 ~ 12.0%	4.0 ~ 12.0%	4.0 ~ 12.0%
Type 2906	4.0 ~ 7.5%	4.0 ~ 7.5%	4.0 ~ 7.5%
Type 2910	7.0 ~ 12.0%	7.0 ~ 12.0%	7.0 ~ 12.0%

+ : The detailed account omitted.



Chemical Structure



R = -H, -CH_3, $\left[-CH_2CH(CH_3)-O- \right]_n H$

Grade Nomenclature

Normal Grade

A	N	6		
B	N	4		
C	N	10T		
C	N	10T	Plus	Plus grade for advanced sustained release

Substitution

A	HPMC 2910
B	HPMC 2906
C	HPMC 2208

Viscosity

M	X 10
H	X 100
U	X 1,000
T	X 10,000

Functional Categories

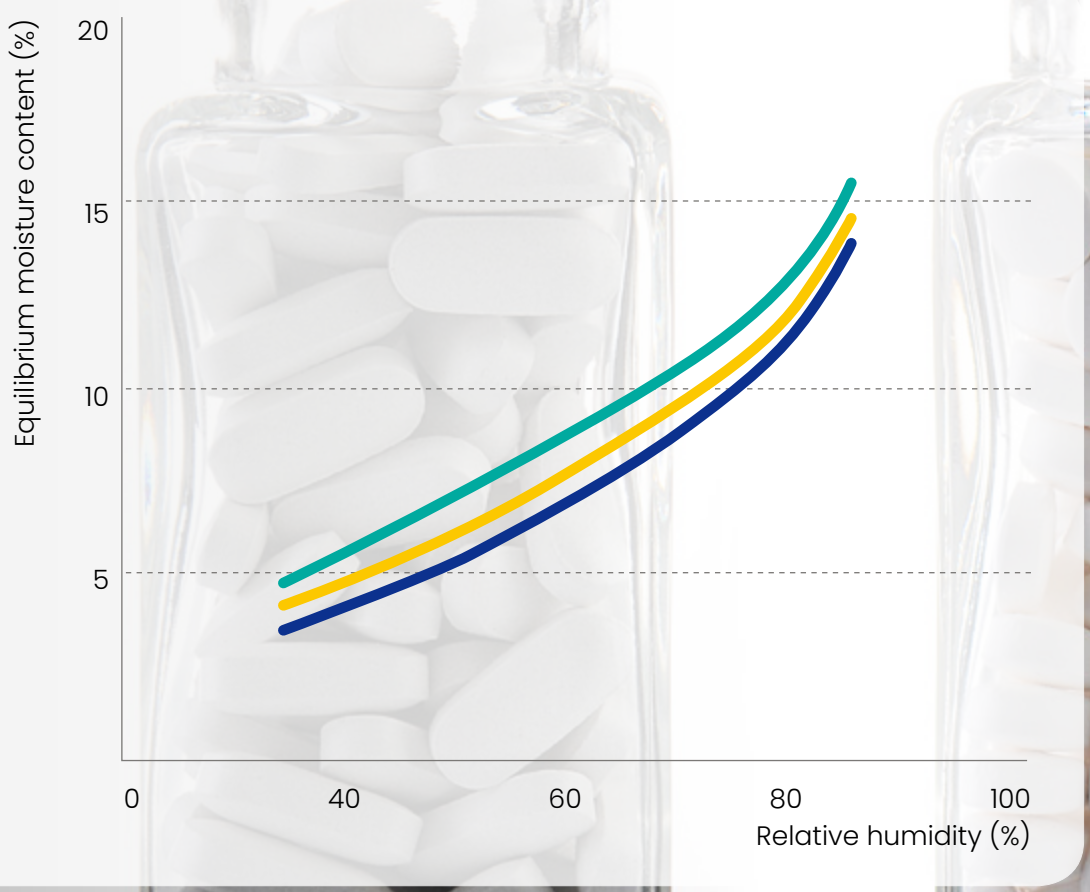
	Effects	Usage	Recommendable grade
Film Coating Aqueous Solvent	Once soluble in water and volatilized through solvent, AnyCoat® makes transparent film with high tensile strength	1 ~ 5% (coating solution 5 ~ 15%)	AN3 AN4 AN5 AN6 AN15
Capsule making	AnyCoat® delivers excellent film forming and gelling property, making high quality capsule	80 ~ 97%	AN4 / AW4 AN5 AN6 / AW6 BN4
Sustained Release	Hydrophilic matrix used along with AnyCoat® hydrates to create a gel layer, controlling drug release pattern	10 ~ 80%	CN10M / Plus CN40H / Plus CN15U / Plus CN10T / Plus AN40H / Plus
Binder (Wet Granulation)	AnyCoat® delivers binding property, and enhances the hardness of tablet	2 ~ 5%	AN3, AN4 AN5, AN6 AN15, AN50 BN4, BN50
Thickening	AnyCoat® provides the thickening property. The viscosity of AnyCoat® exponentially increases in relation to the concentration	0.25 ~ 5%	BN50, BN40H CN10M, CN40H CN15U, CN10T
Solid Dispersion	As a suspending aid and drug carrier for solid dispersion, AnyCoat® provides excellent properties	5% ~	AN3, AN4 AN5, AN6 AN15, BN4

AnyCoat-C Powder

Equilibrium Moisture Content in Relation to Relative Humidity

Equilibrium moisture content refers to the moisture content of AnyCoat-C powder which reaches equilibrium while exposed to specifically set relative humidity for long.
The figure below is used as an indicator to predict the moisture content of AnyCoat-C stored for long.

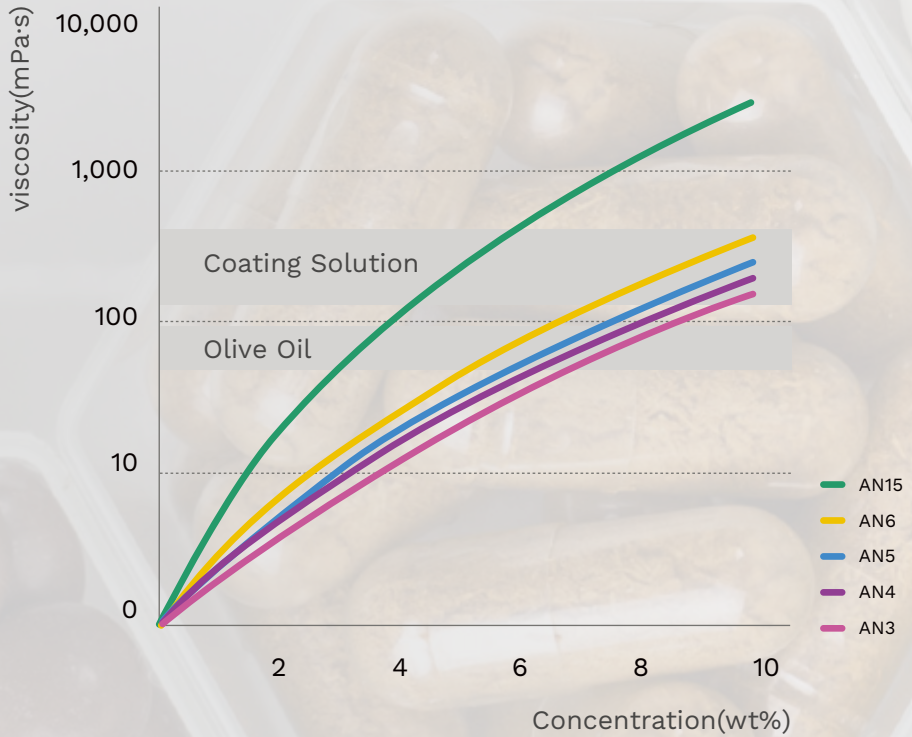
- 2208 type, 4,000mPa·s
- 2906 type, 4,000mPa·s
- 2910 type, 4,000mPa·s



Properties of AnyCoat-C Solution

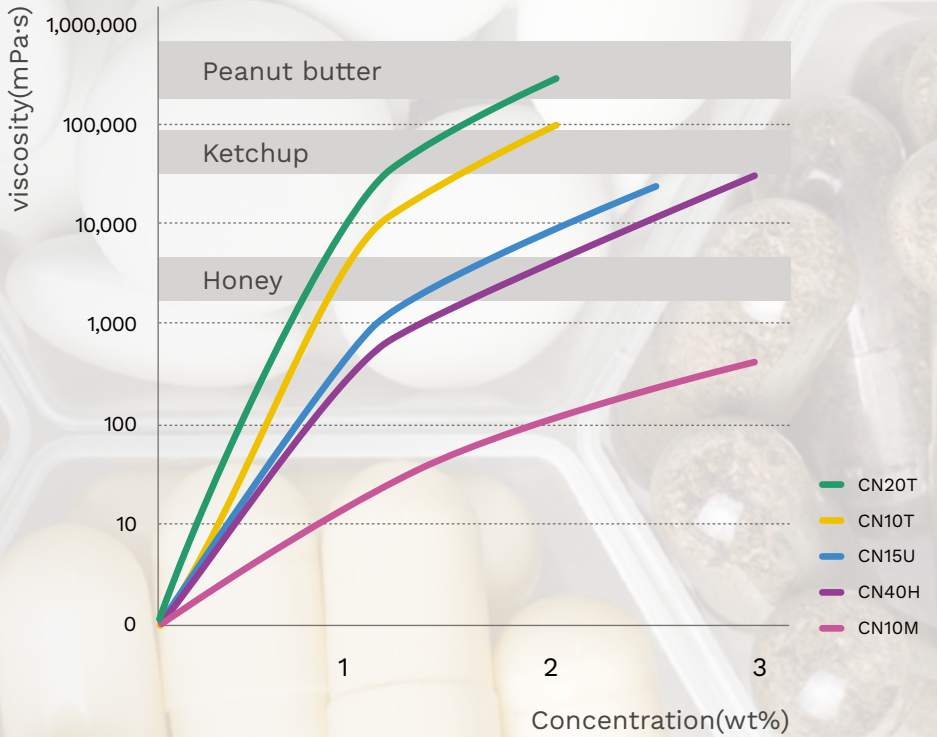
Concentration/Viscosity Relationship

600mPa·s under : Ubbelohde viscometer,
600mPa·s over : Brookfield viscometer, 20°C



Concentration/Viscosity Relationship

600cps under : Ubbelohde viscometer,
600cps over : Brookfield viscometer, 20°C



AnyCoat-P

General Characteristics

CAS number	9050-31-1
Chemical name	Cellulose, 2-hydroxypropyl methyl ether phthalic acid ester
Generic name	Hypromellose phthalate, Hydroxypropylmethylcellulose phthalate
Molecular weight	20,000 ~100,000
Bulk density	0.31 ~ 0.42 g/ml
Angle of repose	33 ~ 38°
Admission to compendium	USP/NF, EP, BP, JP, KP etc.

Specifications

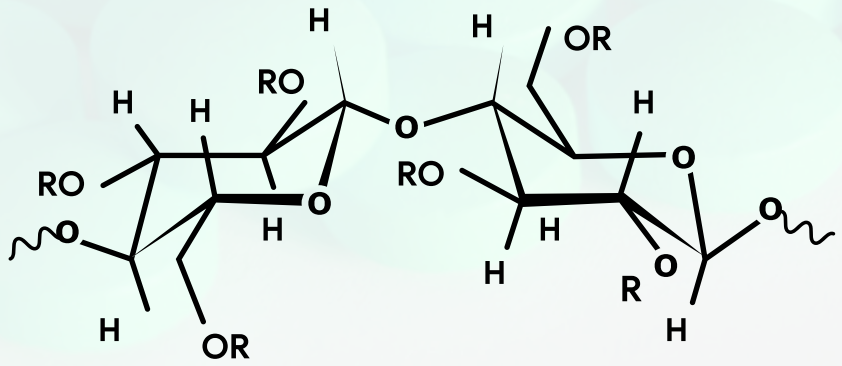
Test	USP-NF 2021	EP10	JP18
Identification	+	+	+
Characters		+	
pH	5.0 ~ 8.0	5.0 ~ 8.0	5.0 ~ 8.0
Apparent viscosity	80 ~ 120% of the normal value	80 ~ 120% of the normal value	80 ~ 120% of the normal value
Water	≤ 5.0%	≤ 5.0%	≤ 5.0%
Residue on ignition	≤ 0.2%	≤ 0.2% (Sulfated ash)	≤ 0.2%
Heavy metals	-	-	≤ 10ppm
Chlorides	≤ 0.07%	≤ 0.07%	≤ 0.07%
Phthalyl content	21.0 ~ 35.0%	21.0 ~ 35.0%	Type 200731 : 27.0 ~ 35.0% Type 220824 : 21.0 ~ 27.0%
Free phthalic acid	≤ 1.0%	≤ 1.0%	≤ 1.0%

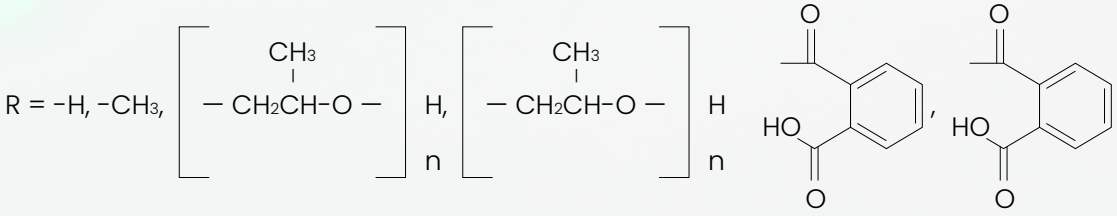
+ : The detailed account omitted.

Chemistry of AnyCoat-P

Test	HP-55	HP-50
Substitution Type	200731	220824
Viscosity (mm^2/s)	32 ~ 48	44 ~ 66
Phthalyl (%)	27.0 ~ 35.0	21.0 ~ 27.0
Insoluble pH range	Less than 5.5	Less than 5.0

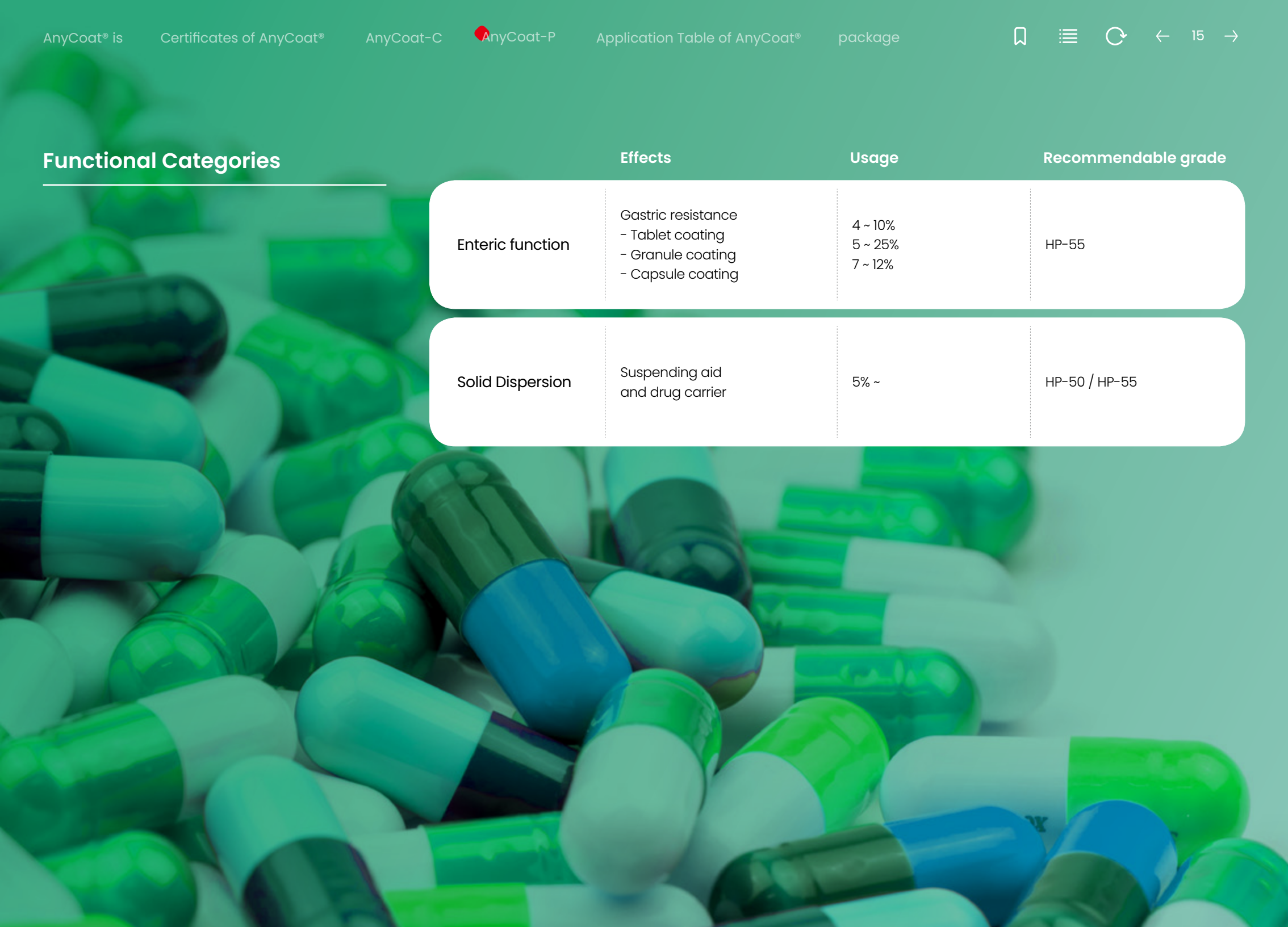
Chemical Structure





Functional Categories

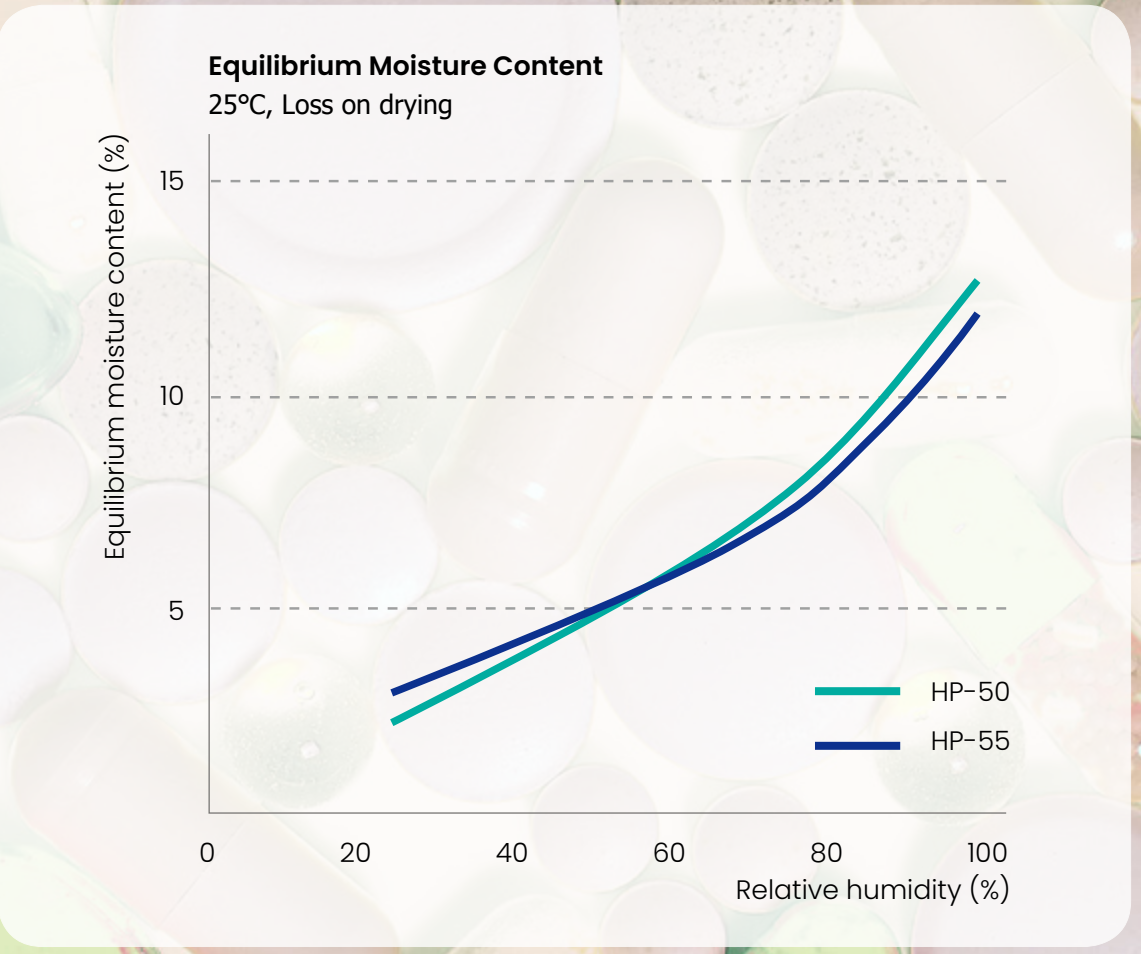
	Effects	Usage	Recommendable grade
Enteric function	Gastric resistance - Tablet coating - Granule coating - Capsule coating	4 ~ 10% 5 ~ 25% 7 ~ 12%	HP-55
Solid Dispersion	Suspending aid and drug carrier	5% ~	HP-50 / HP-55



Properties of AnyCoat-P Powder

Equilibrium Moisture Content in Relation to Relative Humidity

Equilibrium moisture content refers to the moisture content of AnyCoat-P powder which reaches equilibrium while exposed to specifically set relative humidity for long.
The figure below is used as an indicator to predict the moisture content of AnyCoat-P stored for long.

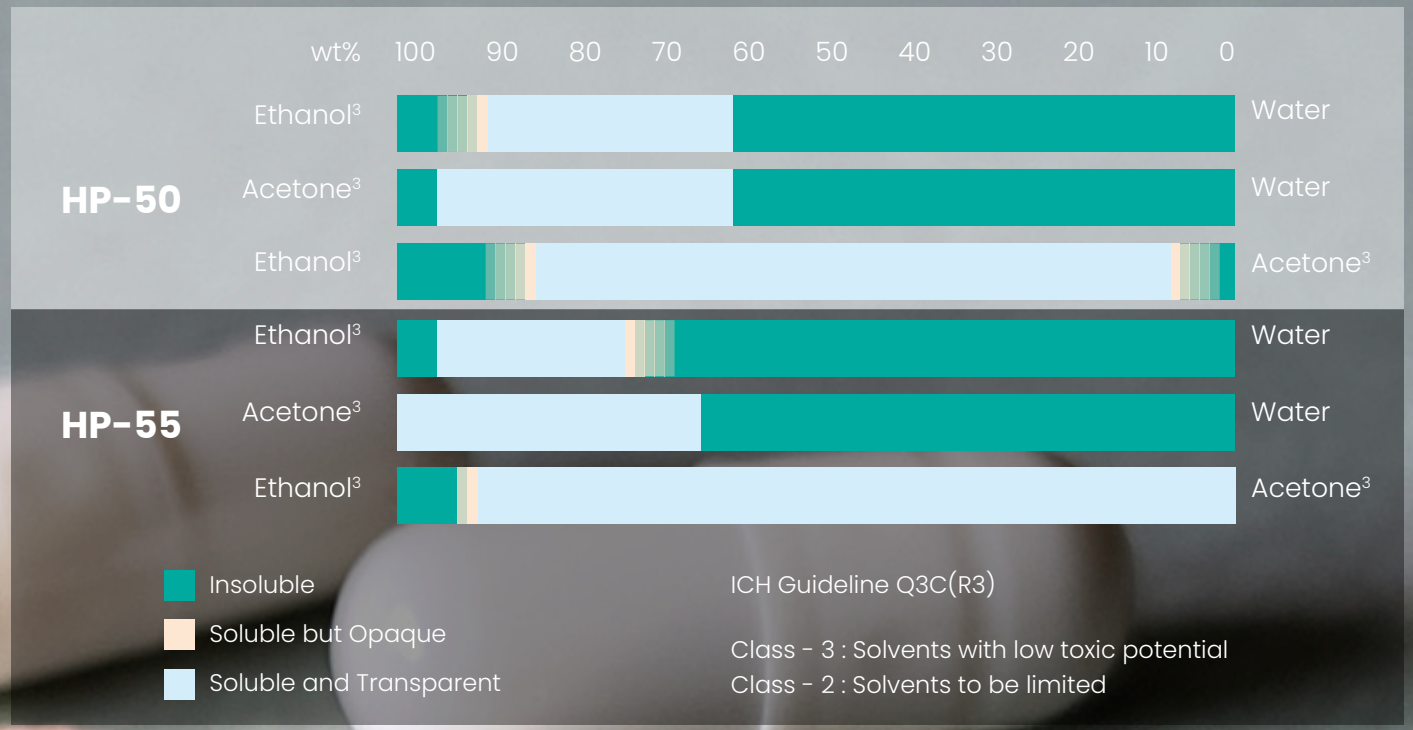


Properties of AnyCoat-P Solution

Solubility in Organic Solvent

AnyCoat-P should be dissolved into organic solvent for enteric coating. The solubility of AnyCoat-P based on solvent and mixing ratio, primarily used for enteric coating, is summarized on the figure below.

The frequently used plasticizer for AnyCoat-P is PEG 6000~8000, triethyl citrate, acetylated monoglycerides, and so on. In general, 10 to 25% against polymer is added.



Application Table of AnyCoat®

Viscosity	HPMC[1]			HPMCP[2]	
	2910(AN)	2906(BN)	2208(CN)	50	55
3	AN3			O (65mPa·s)	O (43mPa·s)
4	AN4 / AW4[3]	BN4			
5	AN5				
6	AN6 / AW6[3]				
15	AN15				
50	AN50	BN50			
100(10M)			CN10M / Plus[4]		
4,000(40H)	AN40H / Plus[4]	BN40H	CN40H / Plus[4]		
15,000(15U)			CN15U / Plus[4]		
100,000(10T)			CN10T / Plus[4]		

1) Viscosity : 2%, 20°C, USP
2) Viscosity : 10% @Methyl chloride : Methanol = 1:1, 20°C, USP
3) White grade, for lower yellowness
4) Plus grade, for advanced controlled release

Advantages of AnyCoat-C Plus Grades are as following :

- Optimized particle size distribution for controlled release
- Excellent reproducibility in tablet properties, such as weight and content uniformity
- Significantly improved flow properties, providing excellent processibility for direct compression
- Great tablet hardness in the granulation process

Advantages of AnyCoat-C Plus Grades are as following :

Grade		CN10M Plus	CN40H Plus	CN15U Plus	CN10T Plus	AN40H Plus
Viscosity (mPa·s)	Label	100	4,000	15,000	100,000	4,000
	Range	80~120	3,000~5,600	11,250~21,000	75,000~140,000	3,000~5,600
MeO(%)		22 ~ 24				28 ~ 30
HPO(%)		7.5 ~ 9.5		8.5 ~ 10.5	9.5 ~ 11.5	8.5 ~ 10.5
#230M ↓ (%)		50 ~ 80				

Package

Package

Fiber drum with polyethylene double bag inside

Net Weight

AnyCoat-C : 2910type - 25kg,
2906 & 2208type - 20kg

AnyCoat-P : 20kg

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