

# AMSTER

#### **About Amster Company**

Amster microcell was established in 2018 to manufacture superior quality of Spray dryer Microcrystalline cellulose powder with a team of highly qualified and experienced in the fields of Pharmaceutical excipients. The company is known for its great expertise in manufacturing and supplying of excipient and its derivative products. Our expertise comes from the long experience that we have in the industry and the advanced technologies that we employ in our facilities. Our main motto is to provide the high quality at the reasonable rate..

The Plant is constructed with fully automated process from initial to finish to avoid human handling and to avoid the risk of production contamination.

#### **Quality is Our Priority**

Amster focuses to manufacture high quality of Mccp. We focus on time-sensitive deliveries, efficient marketing, and accurate packaging, and competitive pricing. We believe in providing a positive working culture to staff to bring best practices, expand their product knowledge while driving in all aspects of our work.

#### **Our Vision**

Our vision to make Amster Microcell, a leading pharmaceutical company in excipients and its derivative products across the globe, and to become the most, admire leader in the globe by providing qualitative, core leadership and a customer-first approach.

#### **Our Mission**

Our mission is to provide total customer satisfaction and achieve leadership in chosen markets, products, and services across the globe, through excellence in technology and using the high-quality raw material and best research and development in house.

We take social responsibility of delivering the highest standard products to all segments of society without compromising on our core values of integrity, good ethics, and commitment

### **Quality Policy**

Amster Microcell Private Limited strongly believe that quality is the bedrock of every action we undertake. Our customers associate with us because of the qualitative nature of the products. We have institutionalized a stringent quality check mechanism to ensure that every product we roll out is in complete alignment with our customers expectations.









Parameters	Specification
Color	White
Solubility	Practically insoluble in water, dilute acid and most of organic solvents, Slightly soluble in dilute NaOH solution
Identification A (USP/BP), B (EP),1 (JP)	Have to correspond as USP/NF, JP,Ph.Eur.,BP
Identification A (EP)	Have to correspond as Ph. Eur.
Identification B (USP/BP), 3(JP), C (EP) (Degree of Polymerization)	NMT 350 as USP/NF,JP,Ph.Eur.,BP
Identification 2 (JP)	Have to correspond as JP
Solubility (coppertetramine solution)	Have to correspond as Ph.Eur., BP
рН	5.0-7.5 asUSP/NF,JP,Ph.Eur.,BP
Conductivity	NMT 75 µS.cm-1as USP/NF,JP,Ph.Eur.,BP
Water- Soluble Substance	NMT 0.25% as USP/NF,JP,Ph.Eur.,BP
Ether- Soluble Solution	NMT 0.05% as USP/NF,JP,Ph.Eur.,BP
Loss on Drying	NMT 7.0% as USP/NF,JP,Ph.Eur.,BP
Heavy Metals	NMT 10 PPM as USP/NF,JP,Ph.Eur.,BP
Residue on Ignition/Sulphated Ash	NMT 0.1% as USP/NF,JP,Ph.Eur.,BP
Residue on Ignition/Sulphated Ash	NMT 0.1% as USP/NF,JP,Ph.Eur.,BP
Organic volatile Impurities	To comply the tests as per method IV. (USP)
Assay (Dried)	97.0 – 102.0(IP)
Arsenic	NMT 2 PPM as IP
Starch & Dextrin	Should comply the test as IP
Organic Impurities	Should comply the test as IP

#### MICROBIAL LIMITS

WITCH CODING ENWITE	
Total Viable Aerobic Count	N.M.T. 1000/g as USP/NF, Ph.Eur., BP
Total yeast& Mould Count	N.M.T 100/g as USP/NF, Ph.Eur., BP
Staphylococcus aureus	Absent as USP/NF, Ph.Eur., BP
Escherichia Coli.	Absent asUSP/NF, Ph.Eur., BP
Pseudomonas aeruginosa	Absent as USP/NF, Ph.Eur., BP
Salmonella species	Absent as USP/NF, Ph.Eur., BP

The raw materials, manufacturing process, and product do not contain any of solvents listed in Organic Volatile Impurities (USP<467>) & residual solvents (Ph - Eur<5.4> Storage recommendation: Preserve in tight containers.



Grade	Usage
AMCELL-101	AMCELL-101 is most widely used for direct compression tableting and wet granulation.
AMCELL-102	AMCELL-102 has similar compression properties to AMCELL-101. However, it has larger particle size and therefore, may be of value in improving the flow if fine powders.
AMCELL-12	AMCELL-12 has larger particle size and therefore, value in improving the flow property.
AMCELL-103 AMCELL- 112 AMCELL-113 AMCELL-200 LM AMCELL-14	AMCELL-103, AMCELL-112, AMCELL-113, AMCELL-200 LM and AMCELL-14 have reduced moisture content and are ideal for use with moisture sensitive materials.
AMCELL-105	AMCELL-105 has the finest particle size and may be used in direct compressing of coarser, granular and crystalline materials. AMCELL-105's enhanced compressibility characteristics make it ideally suitable for application involving difficult to compress materials. It can be admixed with AMCELL-101 or AMCELL-102 to achieve specific flow and/or compression properties.
AMCELL-200	AMCELL-200 has a large particle size which offers increased flow ability with minimum effect on compression characteristics. It can be used in direct compression and wet granulation to reduce table weight variation and to improve content uniformity.
AMCELL-250	AMCELL-250 has a large particle size than AMCELL 200 which offers increased flow ability with minimum effect on compression characteristics than AMCELL 250.
AMCELL-301	AMCELL-301 has a higher density then its size equivalent, AMCELL-101, providing increased flow ability, greater tablet weight uniformity and the potential for making smaller tablets.
AMCELL-302	AMCELL-302 has the density characteristics of AMCELL-301 with a particle size of AMCELL-102. Like AMCELL-301, AMCELL-302 offers increased flow ability, greater tablet weight uniformity and the potential for smaller tablets.



	PARTICLE SIZE DISTRIBUTION				BULK DENSITY	MOISTURE	PARTICLE SIZE		
GRADES	D10	D50	D90	APS#	(GM/ML)	(%WW)	> 60 MESH	> 100 MESH	> 200 MESH
	(MIC)	(MIC)	(MIC)	(MIC)					
AMCELL101	≤30	40-60	≥80	50	0.26-0.34	NMT 7.0%	≤ 1 %	-	≤ 30 %
AMCELL102	≤45	70-100	≥140	90	0.27-0.34	NMT 7.0%	≤ 8 %		≥ 45 %
AMCELL103	≤30	40-60	≥80	50	0.26-0.34	NMT 3.0%	≤ 1 %	-	≤ 30 %
AMCELL105	02 – 10	10 - 30	20 - 60	20	0.20-0.30	NMT 5.0%	Passes throu	ugh 400 Mesh	≥ 90 %
AMCELL112	≤45	70-100	≥140	90	0.28-0.34	NMT 1.5%	≤ 8 %	-	≥ 45 %
AMCELL12	≤50	100- 140	≥200	110	0.27-0.34	NMT 7.0%	38 Mesh ≤	94 Mesh ≤	300 Mesh
AMCELL14	≤50	100- 140	≥200	110	0.27-0.34	NMT 1.5%	0.5%	50 %	≥ 70%
AMCELL113	≤30	40-60	≥80	50	0.28-0.34	NMT 1.5%	≤ 1 %	-	≤ 30 %
AMCELL200	≤70	150- 200	≥260	180	0.31-0.39	NMT 7.0%	≥ 10 %	≥ 50 %	-
AMCELL200 LM	≤70	150- 200	≥260	180	0.31-0.39	NMT 1.5%	≥ 10 %	≥ 50 %	-
AMCELL250	-	-	-	-	0.31-0.39	NMT 7.0%	≥ 30 %	≥ 60 %	-
AMCELL301	≤30	40-60	≥80	50	0.35-0.45	NMT 7.0%	≤ 1 %	-	≤ 30 %
AMCELL302	≤45	70-100	≥140	90	0.35-0.45	NMT 7.0%	≤ 8 %	-	≥ 45 %
AMCELL101 FP	≤30	40-60	≥80	50	0.26-0.34	NMT 5.0%	≤ 1 %	-	≤ 30 %
AMCELL102 HD	≤45	70-100	≥140	90	0.30-0.36	NMT 7.0%	≤ 8 %	-	≥ 45 %

•	a.	Brightness	for	all	grades :	= >88%
_	u.	DIIGITUTOSS	101	un	grades	- 00 /0

a. Brightness for all grades = >88%b. Black particles per 600cm2< 08 Nos. Max.</li>

GRADES	PARTICLE SIZE DISTRIBUTION				BULK DENSITY	MOISTURE	PARTICLE SIZE		
	D10	D50	D90	APS#	(GM/ML)	(%WW)	> 60 MESH	> 100 MESH	> 200 MESH
	(MIC)	(MIC)	(MIC)	(MIC)		(//////////////////////////////////////			
AMCELL101 PLUS	≤30	40-60	≥80	50	0.26-0.31	3.0 - 5.0%	≤ 1 %	-	≤ 30 %
AMCELL102 PLUS	≤45	70-100	≥140	90	0.28-0.33	3.0 - 5.0%	≤ 8 %		≥ 45 %
AMCELL103 PLUS	≤30	40-60	≥80	50	0.26-0.31	NMT 3.0%	≤ 1 %	-	≤ 30 %
AMCELL105 PLUS	02 – 10	10 - 30	20 - 60	20	0.20-0.30	NMT 5.0%	Passes through 400 Mesh ≥ 99.5 %		
AMCELL112 PLUS	≤45	70-100	≥140	90	0.28-0.33	NMT 1.5%	≤ 8 %	-	≥ 45 %
AMCELL12 PLUS	≤50	100- 140	≥200	110	0.28-0.33	3.0 - 5.0%	38 Mesh ≤	94 Mesh ≤ 50 %	300 Mesh ≥ 70%
AMCELL14 PLUS	≤50	100- 140	≥200	110	0.28-0.33	NMT 1.5%	1 %		
AMCELL113 PLUS	≤30	40-60	≥80	50	0.26-0.31	NMT 1.5%	≤ 1 %	-	≤ 30 %
AMCELL200 PLUS	≤70	150- 200	≥260	180	0.31-0.39	3.0 - 5.0%	≥ 10 %	≥ 50 %	-
AMCELL250 PLUS	-	-	-	-	0.31-0.39	3.0 - 5.0%	≥ 30 %	≥ 60 %	-
AMCELL301 PLUS	≤30	40-60	≥80	50	0.35-0.45	3.0 - 5.0%	≤ 1 %	-	≤ 30 %
AMCELL302 PLUS	≤45	70-100	≥140	90	0.35-0.45	3.0 - 5.0%	≤ 8 %		≥ 45 %

<sup>•</sup> a. Brightness for all grades = >92%

<sup>•</sup> c. NMT- Not more than

<sup>•</sup> b. Black particles per 600cm2< 03 Nos. Max.

## **Application**

#### (1) PHARMACEUTICALS



- Filler
- Binder
- Disintegrant
- Lubricant

#### (2) **FOOD**



#### I. Bakery

- Anticaking agent
- Fat replacement
- Heat stabilizer
- Flow control
- Excellent creamy mouth Bulking agent
- Flavour release
- Prevent separation of oil & water
- Improved texture



#### II. Fluids

- Suspension stabilizer
- Improves creaminess
- Fat replacement
- Improves mouth feel
- Flavour release
- Opacifier
- Heat stabilizer



#### III. Dairy

- Ice crystal control
- Texture modification
- Lower fat
- Form stabilizer
- Prevent water loss
- Emulsion stabilizer
- Opacifier



#### **IV. Extrusition**

- Low calorie
- Improves texture
- Moisture control Heat stabilizer



#### V. Vegetarian Food

- Frozen thaw stabilizer
- Improve mouth feel
- Moisture control

#### (3) COSMETIC



- Thickener
- Binder
- Abrasive
- Absorbent Adhesive
- Anticaking agent
- Bulking agent
- Emulsion stabilizer
- Opacifying agent
- Slip modifier

#### (4) WELDING ELECTRODES



- Binder
- Prevent cracks on body of
- Provide good texture
- Provides inert gas atmosphere at the time of welding.

#### (5) PAINTS



- Thickener
- Controls viscosity
- Emulsifier
- Improve compressive strength
- Absorbs moisture and prevents clogging

#### (6) CEMENT & CERAMICS



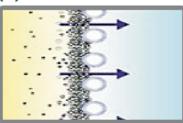
- Improve compressive strength
- Absorbs moisture and prevents clogging

#### (7) RUBBER



- Reduction in mooney viscosity
- Enhance plasticity
- Reduce aromatic oil content
- Can partially replace silica

#### (8) FILTRATION AID



- Used in almost all filtration processes
- Used in petroleum industries as filtering aid, for metal filtration

#### (9) FEED



- To boost the energy content of
- Utilized for energy by ruminants
- Dietary supplement for poultry &
- Additive to animal feed



## In House Research & Laboratory Facility

To comply with compendial monographs we have in house laboratory in our factory. With inclusion of microbial testing

With this its helps us with maintaining our

- Total Quality Management
- Quality Assurance for our clients
- Easy testing of Raw materials and Finshed Products
- Easy record keeping of all batch production
- Confidence about products shelf life and Quality
- Digital Testing method















- FDA approved
- ISO 9001:2015
- GMP Certificate
- GLP Certificate
- Kosher Certificate (Under process)
- Halal Certificate (Under process)
- Non- GMO
- USP/NF, BP, EP, JP, IP compliance











#### **AMSTER MICROCELL PVT.LTD**

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