

Avicel® RC-591
Microcrystalline Cellulose and
Carboxymethylcellulose Sodium, NF, BP

**Pharmaceutical Emulsions
and Suspensions**
Stabilization Technology For Liquid
And Semi-Solid Dosage Forms

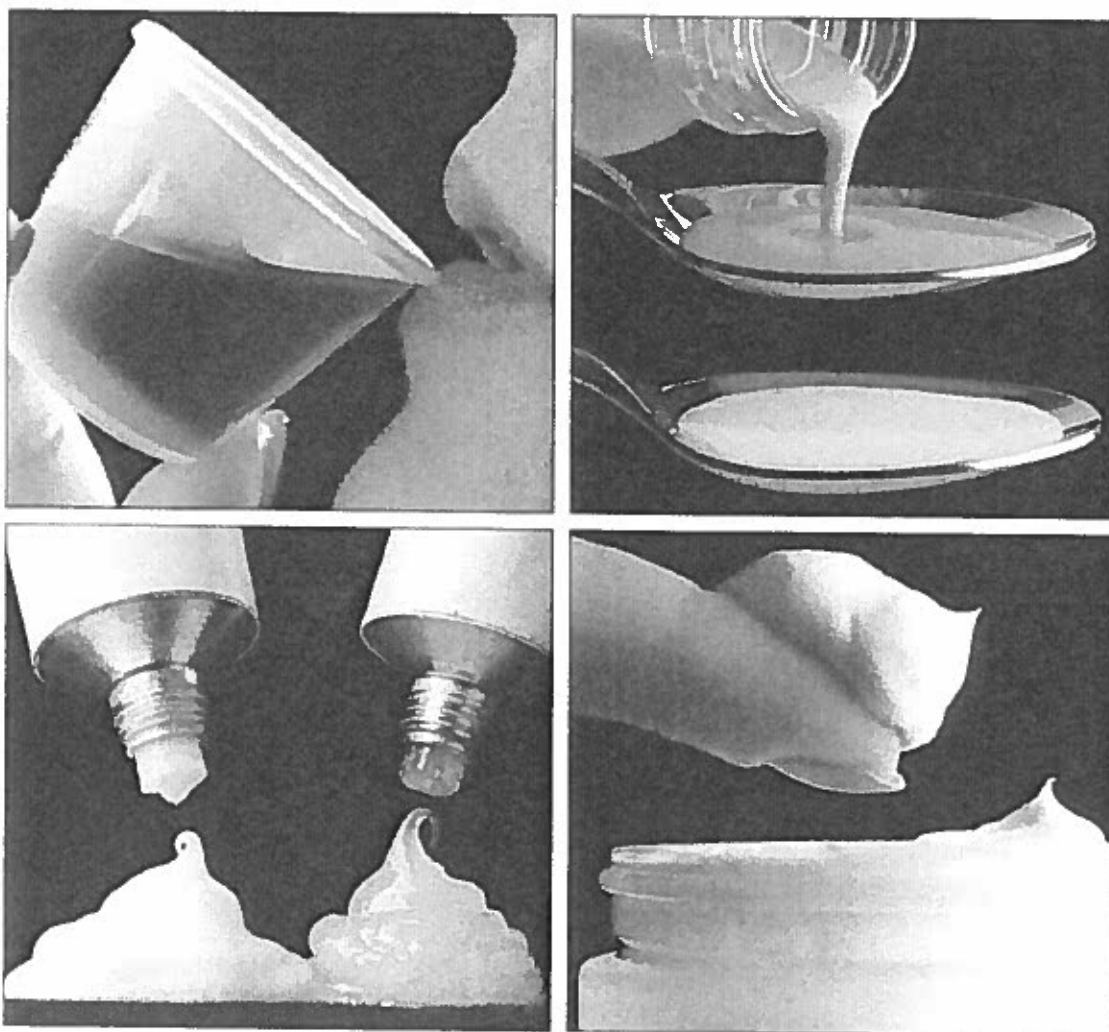
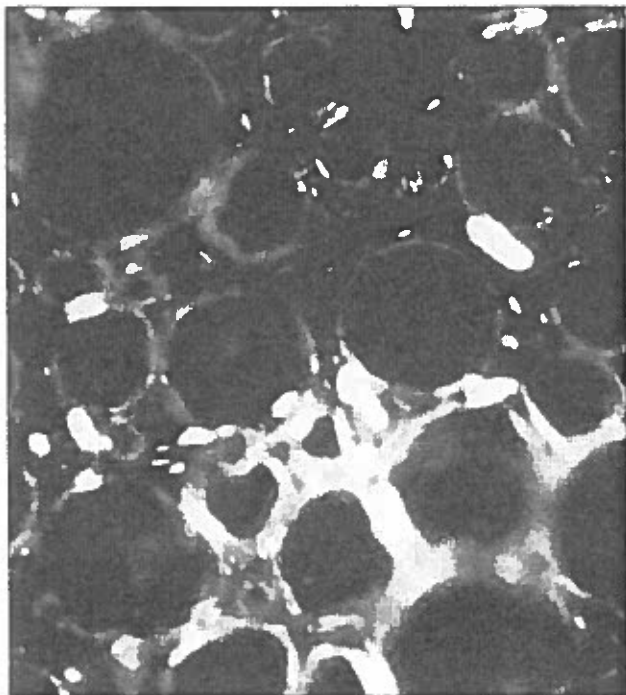


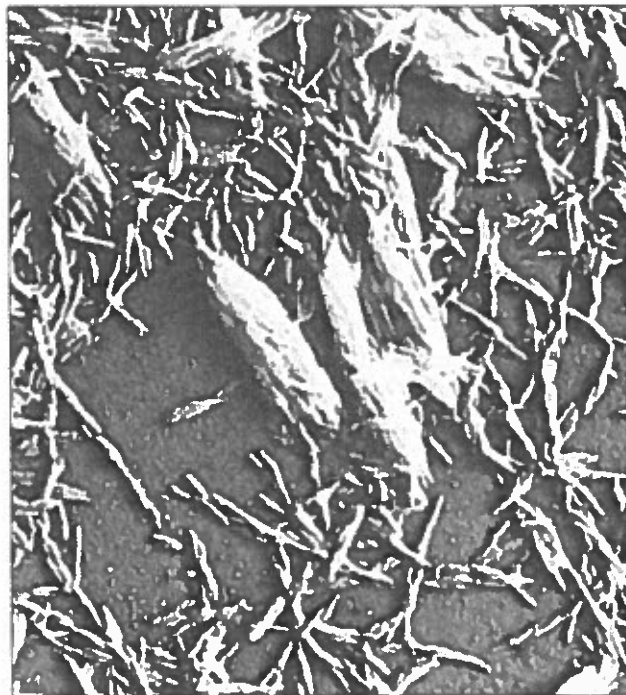
Exhibit 1054

Avicel® RC-591

Microcrystalline Cellulose, NF, BP



Avicel RC-591 emulsion



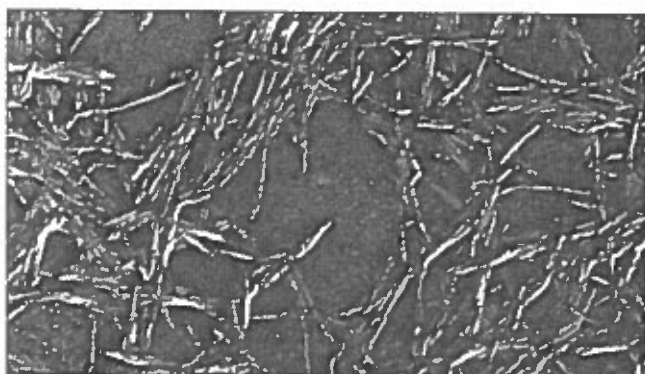
Cellulose microcrystals and crystallite aggregates

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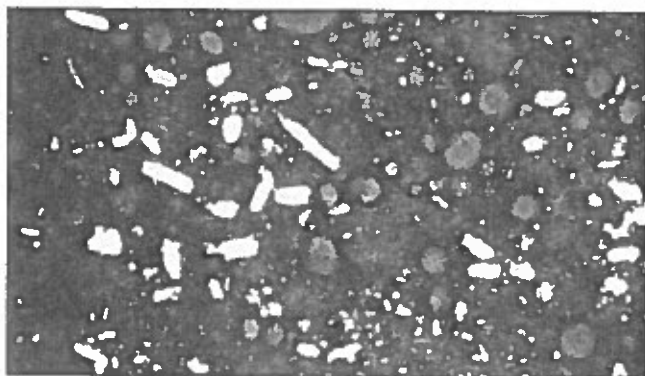
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Advantages of formulating suspensions and emulsions with Avicel® RC-591

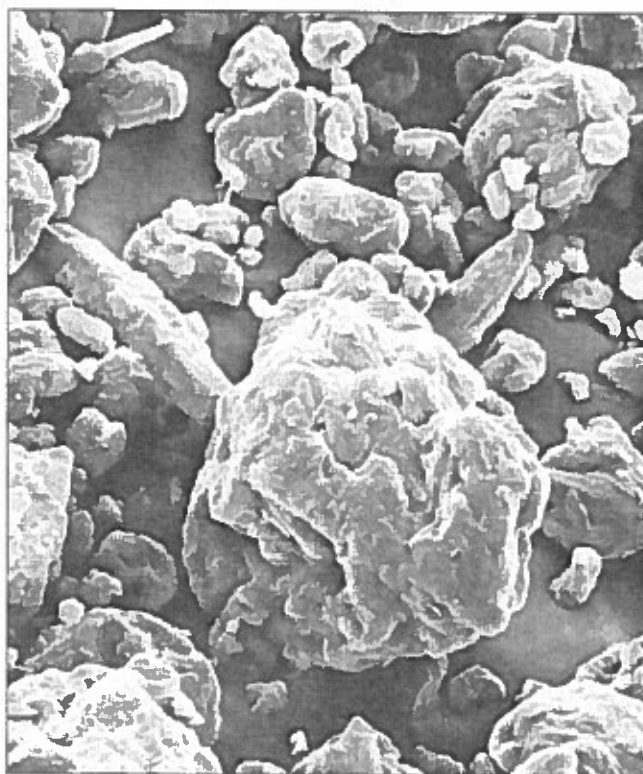
- Viscosity regulator and modifier
- Thixotropic characteristics
- Heat and freeze-thaw stable
- Long shelf-life stability
- Lengthy hydration times eliminated
- Stable at pH range 4-11
- Odorless, tasteless



Avicel Colloidal MCC



Undispersed Avicel RC-591 suspension



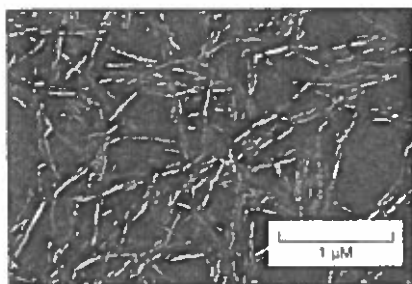
Spray dried Avicel RC-591

600X

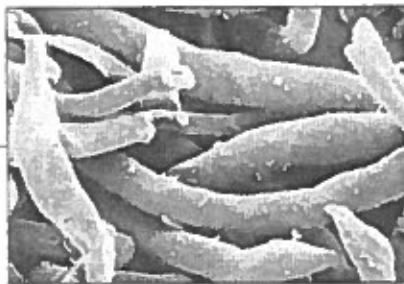
Avicel® RC-591

- A water dispersible organic hydrocolloid used in the preparation of pharmaceutical suspensions and emulsions.
- A spray-dried blend of microcrystalline cellulose (MCC) and sodium carboxymethylcellulose (CMC).

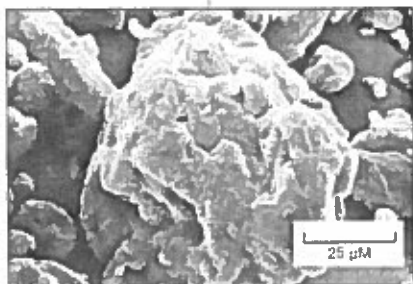
The colloidal MCC provides a structured dispersion vehicle while the CMC facilitates dispersion and serves as a protective colloid.



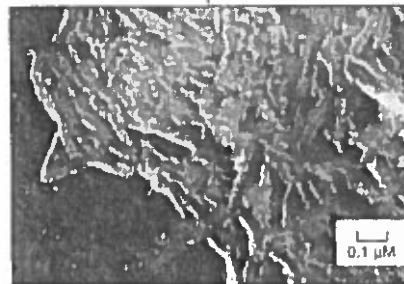
*Avicel Colloidal MCC
(Insoluble component)*



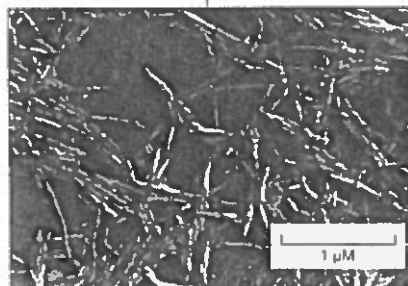
*Sodium carboxymethylcellulose
(Soluble component)*



*Powder particle of
Avicel RC-591*



*Cut powder particle shows tightly
packed microcrystals*



*Aqueous dispersion
of Avicel RC-591*

Structure and Function

Microcrystals of Avicel[®] microcrystalline cellulose are leashed together with chains of soluble CMC to form a mesh-like powder particle (Fig. 1).

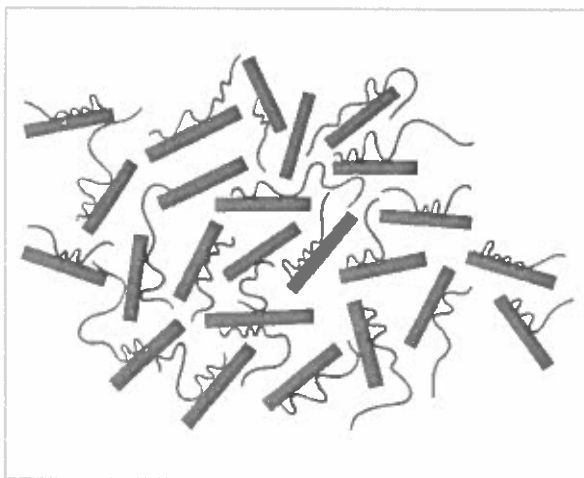


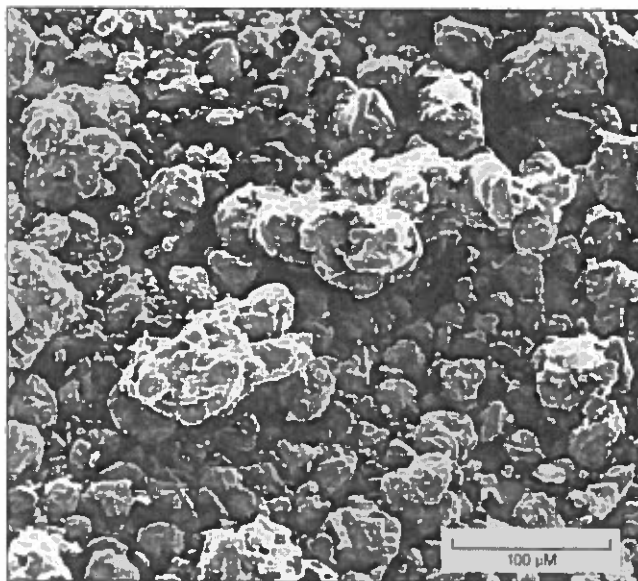
Figure 1.— Powder particle Avicel RC-591

Due to the small size of the microcrystals (approximately 60% of the crystallites in dispersion are $<0.2 \mu\text{M}$), there are a large number of microcrystals packed in each powder particle. (Fig. 2).

The large number of small, microcrystal particles help promote

- Slower more uniform settling rate
- Suspension stability
- Formulation elegance
- Absence of hard packing

The highly compact nature of the powder particle is evident in this scanning electromicrograph (Fig. 3).



Avicel RC 591 powder particles

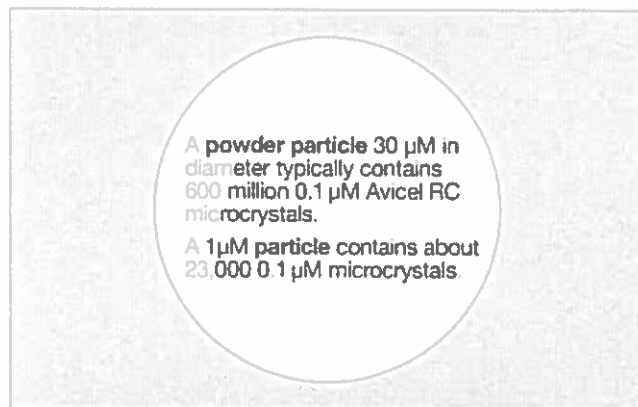


Figure 2.— Colloidal powder particle

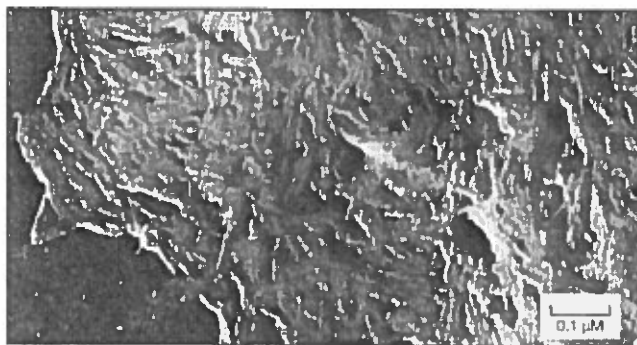


Figure 3.— Cut powder particle

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