

CYTEC



DOCUSATE Sodium **A Pharmaceutical Grade Surfactant** **2009**

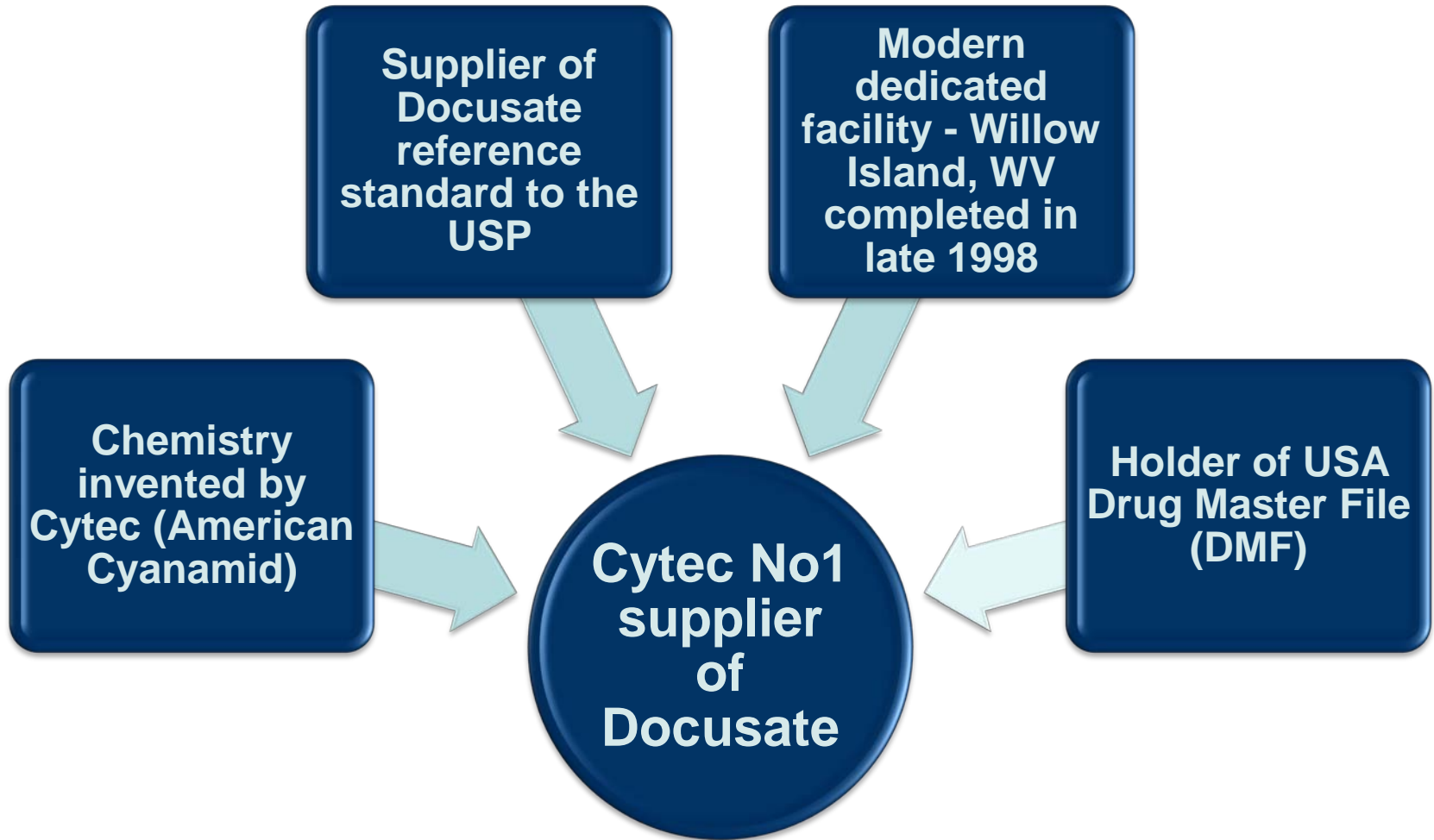


**DOCUSATE SODIUM
USP**

**Pharmaceutical grade
surfactant**

**Sodium dioctyl
sulfosuccinate**

Cytec your first choice for Docusate



Dedicated Manufacturing Facility

ISO 9001 certified

cGMP facility

**Regulated
manufacturing
facility**

**Largest Docusate
production site**

**FDA registered &
inspected**

DOCUSATE Product Offering

**Docusate
100**

- A 100% waxy solid.

DSS 85

- A 85% active powdered material with sodium benzoate.

**DSS 50%
PEG**

- A 50% active material in PEG (polyethylene glycol).

Status of DOCUSATE

Material meets USP,
EP and JPC codex
specifications

Meets/exceeds the
requirements of ICH
Q7A Guidelines

Compliance

BSE/TSE Compliant

100% and 50%
products are Kosher
certified by Orthodox
Union

Dedication to Quality

+50 Years Manufacturing History

- Exceptional consistency, batch to batch.
- Outstanding experience.

FDA Registered site

- Subject of regular inspections.
- Ensures site is GMP compliant.

DMF

- Holder of Drug Master File (DMF).
- Our process and product summaries on file with FDA.

ISO 9001

- Certified ISO 9001:2000 by LRQA.
- Audit of quality management systems.

Customer Audits

- Frequent audits by major global pharmaceutical companies.
- Quality systems constantly scrutinized and improved where possible.

Complete Certification Package

- Provided with every shipment.
- Complete traceability of all components.

Applications for DOCUSATE

API

- Active Pharmaceutical Ingredient.
- Used in both OTC and prescription products.

Excipient

- Pharmaceutical quality excipient.
- Due to its surfactants properties has many varied applications.

Stool Softeners & Laxatives.

- Capsules, tablets or liquids.
- Highly effective active ingredient for a variety of laxative/stool softener formulations.
- Can be used alone or in combination with peristaltic stimulants and bulking agents.



Prenatal and geriatric vitamin preparations.

- To counteract constipation induced by consumption of iron salts.



A Pharmaceutical Grade Excipient

Applications.

- Tableting Aid.
- Liquid or Gel Suspensions.
- Effervescent Tablets.
- Emulsifier for Creams and Gels.
- Enema/Pre-Operative Colon Cleaners.
- Iron Preparations.
- Ear Wax Removal.
- Sustained Release Dosage Forms.
- Transdermal Patches.



Benefits.

- Excellent solubilizing, wetting, dispersing and emulsifying properties.
- Low order of toxicity.
- Stability and compatibility with a wide range of pharmacologically active drugs.
- Proven results in many different pharmaceutical products.



Formulating Aid for Oral Dosages

Excellent wetting, solubilizing, dispersing and emulsifying agent.

- Aids wet granulation of hydrophobic powders.
- Facilitates tablet coating.
- Only small amount required as tableting aid.
- Promotes therapeutic efficacy through uniform diffusion.
- Rapid absorption of active ingredients.
- Improves manufacturing line speed.
- Lowers production costs.
- Improves tablet disintegration and dissolution.
- May eliminate need for separate disintegrating agent.
- Mold release properties help clean release of tablet from the die.



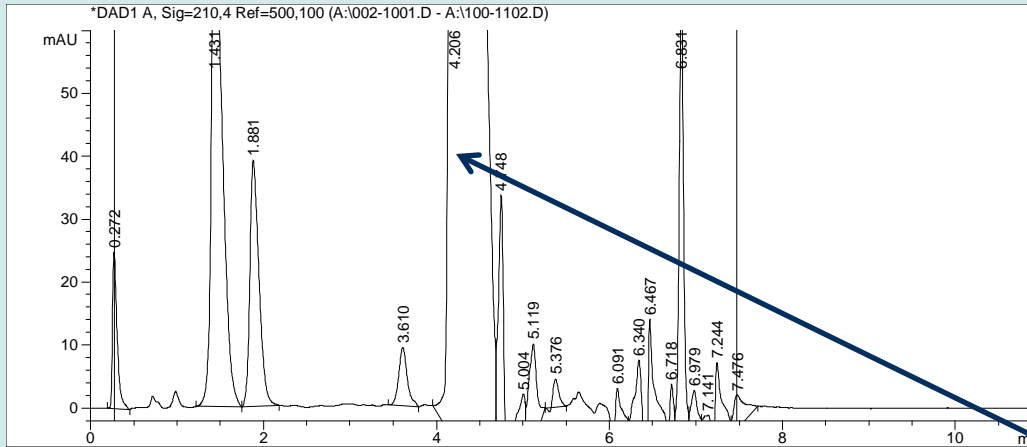
Why source from Cytec?

- **Cytec has the only DMF.**
- **Low impurity profile.**
 - Regulatory agencies worldwide are pushing to quantify impurities industry wide.
 - The impurity profile will become part of the specification.
 - FDA working to have impurity profile in the USP Monograph.
- **Certificate of Suitability filed with EDQM in May 2008.**
- **The Pharmacopeias only cover Docusate Sodium USP 100%.**
 - For other grades you must be able to trace back to active material i.e. Docusate 100% USP.
 - Complete certification package provided with every shipment.



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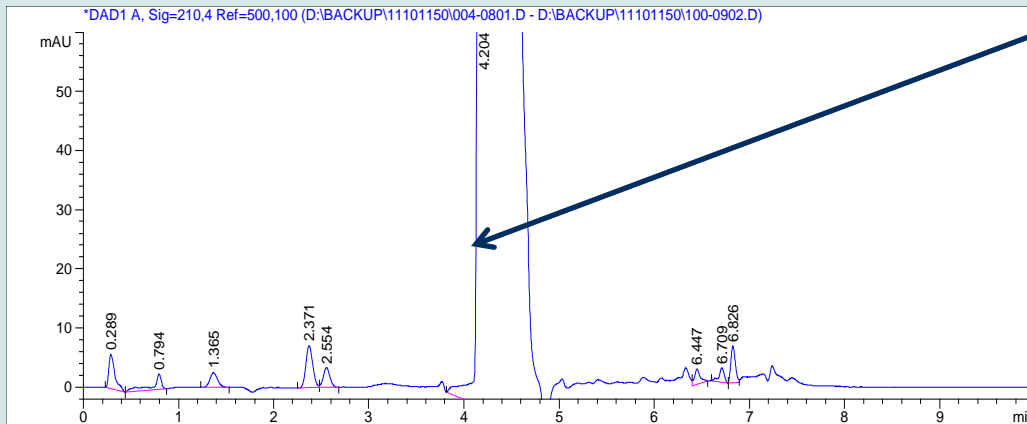
Comparative Impurity Profiles



Competitors material

Sulfonated Compounds Giving Positive Assay Results

Primary Docusate Peak



Cytec material

Impurities <0.5%