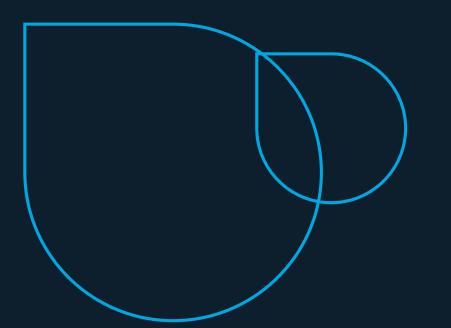


# Outsource Smarter

### Keep Your Pharmacy at the Ready

Critical medications from a partner you can trust.

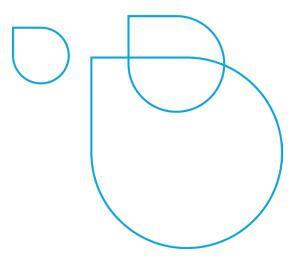


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As a reliable source of high-quality sterile admixtures and pre-filled syringes, we're proud to be your partner in delivering life-saving drugs to those who need them most.

Feel free to reach out should you have any questions about the products listed in this catalog or require assistance in placing your order. We're here to help you make smarter outsourcing decisions, including improved demand planning and optimizing inventory tracking and control.

#### Working together, we will make sure you have the medications you need, when you need them.

## We Are Here For You

Thank you for choosing SCA Pharma to fulfill your 503B outsourcing needs.

## Why SCA Pharma?



We understand that the most effective 503B solution is a partner you can trust. SCA Pharma collaborates with your management team to implement strategies that lower labor costs, reduce drug waste, and keep your pharmacy at the ready while freeing up manpower and resources to focus energy on other things.

A discerning commitment to quality ensures every product in this catalog meets or exceeds cGMP standards. Our lifecycle approach to quality management covers every phase of every process, and each batch SCA Pharma produces must meet stringent release specifications including the following:

- Sterility testing
- Visual Inspection and (Acceptable Quality Limit) AQL
- EM data incorporated into release criteria
- Endotoxin testing
- Potency testing
- Real time stability testing to support Beyond Use Dating
- UV overwrap protection
- Storage conditions



### Understanding SCA Pharma's Compounding Processes

SCA Pharma compounds products using Finished Drug Product (FDP) and API (bulk). The API must appear on the FDA's drug shortage list at the time of compounding, distribution and dispensing. The starting pathway for each individual product is clearly defined in the product list under the "Product Source" heading.

In both processes, safety is achieved through proper application of current Good Manufacturing Practices (cGMP). As an additional measure for sterility assurance, SCA Pharma performs a sterile filtration on all products regardless of starting materials prior to filling into final containers.

#### Finished Drug Product (FDP)

FDP compounding uses an FDA-approved drug as the starting material which is aseptically processed into ready-to-use, single-dose products. This process may also be referred to as compounding from commercial, as the source NDC# can be traced back to a specific commercial drug product.

**Key Characteristics of SCA Pharma FDP Products:** 

- Only FDA-approved commercially available sterile drugs are utilized.
- Source NDC#, traceable to the commercial starting material, is available for every product.
- Only products with a source NDC# traceable to a commercial drug product are delineated as being sourced from an FDP.
- No SCA products labeled as being sourced from FDP are produced from a bulk drug or feature an NDC# traceable to an API. We do not consider sterile filtered or terminally sterilized bulk or pooled products made from API and then filled under sterile aseptic conditions to be from FDP.

#### Active Pharmaceutical Ingredient (API)

A bulk drug substance purchased from an FDA-registered facility is compounded and sterilized to produce ready-to-use, single-dose products. This process may also be referred to as compounding from powder or non-sterile-to sterile compounding, as the source NDC# is traced back to the starting API.

**Key Characteristics of SCA Pharma API Products:** 

- Each API must be accompanied by a Certificate of Analysis and is tested for potency and identity prior to use in compounding.
- The API must appear on the FDA's drug shortage list at the time of compounding, distribution and dispensing; or
- Appear on the FDA's list of bulk drug substances for which there is a clinical need (503B bulks list).

### Products



SCA Pharma works closely with medical facilities to ensure the products we produce match the up-to-date needs of our customers. We currently offer admixed pharmaceuticals in the following categories:

#### Anesthetic

Ketamine Lidocaine

#### Antiarrhythmic

Diltiazem

#### Antibiotic

Vancomycin

#### **Anticoagulant**

Sodium Citrate

#### **Beta-Adrenergic Blocking Agents**

Labetalol

#### Electrolyte

Potassium Chloride **Potassium Phosphate** 

#### Neuromuscular Blocker

Rocuronium Succinylcholine



### **Opioid Analgesic**

Fentanyl Fentanyl + Bupivacaine Fentanyl + Ropivacaine Hydromorphone Methadone Morphine

#### **Oxytocic Agent**

Oxvtocin

#### **Vasopressor**

**Ephedrine** Epinephrine Norepinephrine Phenylephrine



### Product List

NDC



Product Source BUD

## Product List

NDC	Product Description	Product Source	BUD
70004-0200-32	Fentanyl 50 mcg/mL in 100 mL Bag	FDP	105 Days
70004-0202-32	Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 100 mL Bag	API	120 Days
70004-0202-40	Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 250 mL Bag	API	120 Days
70004-213-32	Fentanyl 20 mcg/mL in 0.9% Sodium Chloride 100 mL Bag	API	120 Days
70004-0205-32	Fentanyl 20 mcg/mL in 0.9% Sodium Chloride 100 mL Bag	API	120 Days
70004-0200-22	Fentanyl 50 mcg/mL in 0.9% Sodium Chloride 50 mL fill 60 mL Syringe	API	105 Days
70004-0211-30	Fentanyl 50 mcg/mL in 0.9% Sodium Chloride 50 mL Bag	API	105 Days

#### Fentanyl + Bupivacaine (PF)

70004-0244-40	Fentanyl 2 mcg/mL + Bupivacaine 0.0625% in 0.9% Sodium Chloride 250 mL Bag	FDP	105 Days
70004-0253-40	Fentanyl 2 mcg/mL + Bupivacaine 0.1% in 0.9% Sodium Chloride 250 mL Bag	FDP	105 Days
70004-0231-32	Fentanyl 2 mcg/mL + Bupivacaine 0.125% in 0.9% Sodium Chloride 100 mL Bag	FDP	105 Days
70004-0254-40	Fentanyl 2 mcg/mL + Bupivacaine 0.125% in 0.9% Sodium Chloride 250 mL Bag	FDP	105 Days
70004-0231-22	Fentanyl 2 mcg/mL + Bupivacaine 0.125% in 0.9% Sodium Chloride 50 mL in 60 mL Syringe	FDP	90 Days
70004-0271-22	Fentanyl 2 mcg/mL + Bupivacaine HCl 0.125% in 0.9% Sodium Chloride 50 mL fill 60 mL Syringe	API	90 Days
70004-0231-40	Fentanyl 2 mcg/mL + Bupivacaine 0.125% in 0.9% Sodium Chloride 250 mL Bag	API	105 Days

	Diltiazem		
70004-0541-35	Diltiazem 1 mg/mL (125 mg) in 125 mL 0.9% Sodium Chloride 100 mL Bag (Total Volume 125 mL)	FDP	120 Days
70004-540-35	Diltiazem 1 mg/mL (125 mg) in 125 mL 5% Dextrose 100 mL Bag (Total Volume 125 mL)	FDP	105 Days
	Ephedrine		
70004-0604-09	Ephedrine 5 mg/mL in 0.9% Sodium Chloride 5 mL fill 6 mL Syringe	FDP	90 Days
70004-0604-09-K	Ephedrine 5 mg/mL in 0.9% Sodium Chloride 5 mL fill 6 mL Syringe (Kit Check)	FDP	90 Days
70004-0604-12	Ephedrine 5 mg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe	FDP	90 Days
70004-0604-12-K	Ephedrine 5 mg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe (Kit Check)	FDP	90 Days
70004-0605-09	Ephedrine 10 mg/mL in 0.9% Sodium Chloride 5 mL fill 6 mL Syringe	FDP	90 Days
70004-0605-09-K	Ephedrine 10 mg/mL in 0.9% Sodium Chloride 5 mL fill 6 mL Syringe (Kit Check)	FDP	90 Days

#### Epinephrine

**Product Description** 

70004-613-40	Epinephrine 4 mg (16 mcg/mL) in 0.9% Sodium Chloride 250 mL Bag	FDP	90 Days
70004-608-40	Epinephrine 5 mg (20 mcg/mL) in 0.9% Sodium Chloride 250 mL Bag	FDP	90 Days
70004-607-40	Epinephrine 8 mg (32mcg/mL) in 0.9% Sodium Chloride 250 mL Bag	FDP	90 Days

#### Fentanyl (PF)

70004-0202-22	Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 50 mL fill 60 mL Syringe	FDP	105 Days
70004-0229-32	Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 100 mL Bag	FDP	120 Days
70004-0229-40	Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 250 mL Bag	FDP	120 Days
70004-203-32	Fentanyl 20 mcg/mL in 0.9% Sodium Chloride 100 mL Bag	FDP	120 Days
70004-0200-17	Fentanyl 50 mcg/mL in 25 mL fill 30 mL Syringe	FDP	180 Days
70004-0222-30	Fentanyl 50 mcg/mL in 50 mL DEHP/PVC-Free Bag	FDP	105 Days



### Product List

**Product Description** 

Fentanyl + Ropivacaine (PF)

NDC



### Product List

Product Source	BUD	NDC	Product Description	Product Source	BUD
			Lidocaine		
FDP	105 Days	70004-0720-12	Lidocaine 1% 10 mL fill 12 mL Syringe (PF)	FDP	90 Days
		70004-0723-09	Lidocaine 2% 5 mL fill 6 mL Syringe (PF)	FDP	90 Days
FDP	105 Days	70004-0723-09-K	Lidocaine 2% 5 mL fill 6 mL Syringe (PF) (Kit Check)	FDP	90 Days
API	105 Days				
			Methadone		
		70004-0380-05	Methadone 10 mg/mL 1 mL fill 3 mL Syringe	FDP	105 Days
FDP	105 Days		Morphine		
	105 Davis	70004-0100-16	Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe	FDP	105 Days
		70004-0100-59	Morphine 1 mg/mL in 0.9% Sodium Chloride 100 mL Bag	FDP	105 Days
		70004-0103-16	Morphine 5 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe	FDP	105 Days
	100 Duyo		Norepinephrine		
FDP	105 Days	70004-0781-40	Norepinephrine 4 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	90 Days
FDP	105 Days	70004-0784-40	Norepinephrine 8 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	90 Days
FDP	105 Days	70004-0785-40	Norepinephrine 16 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	190 Days
			Oxytocin		
		70004 005 44	-		
API	90 Days	/0004-085-44	Oxytocin 30 units added to 0.9% Sodium Chioride 500 mL Bag	FDP	60 Days
	FDP API FDP	FDP105 DaysAPI105 DaysFDP105 Days	FDP       105 Days       70004-0720-12         FDP       105 Days       70004-0723-09         API       105 Days       70004-0723-09-K         API       105 Days       70004-0723-09-K         FDP       105 Days       70004-0723-09-K         FDP       105 Days       70004-0723-09-K         FDP       105 Days       70004-0380-05         FDP       105 Days       70004-0100-16         FDP       105 Days       70004-0103-16         FDP       105 Days       70004-0103-16         FDP       105 Days       70004-0781-40         FDP       105 Days       70004-0781-40         FDP       105 Days       70004-0785-40         FDP       105 Days       70004-0785-40         FDP       105 Days       70004-0785-40	FDP       105 Days       Z0004-0720-12       Lidocaine         FDP       105 Days       70004-0723-09       Lidocaine 2% 5 mL fill 6 mL Syringe (PF)         API       105 Days       70004-0723-09       Lidocaine 2% 5 mL fill 6 mL Syringe (PF) (Kit Check)         FDP       105 Days       Methadone       Methadone         FDP       105 Days       Morphine       Morphine         FDP       105 Days       7004-0100-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe         FDP       105 Days       7004-0100-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe         FDP       105 Days       7004-0100-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe         FDP       105 Days       7004-0100-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe         FDP       105 Days       7004-0130-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 250 mL Bag         FDP       105 Days       7004-0781-40       Norepinephrine 4 mg in 0.9% Sodium Chloride 250 mL Bag         FDP       105 Days       7004-0781-40       Norepinephrine 8 mg in 0.9% Sodium Chloride 250 mL Bag         FDP       105 Days       7004-0781-40       Norepinephrine 1 mg in 0.9% Sodium Chloride 250 mL Bag         FD	FDP       105 Days       70004-0720-12       Lidocaine 1% 10 mL fill 12 mL Syringe (PF)       FDP         FDP       105 Days       70004-0723-09       Lidocaine 2% 5 mL fill 6 mL Syringe (PF)       FDP         API       105 Days       FDP       70004-0723-09       Lidocaine 2% 5 mL fill 6 mL Syringe (PF) (Kit Check)       FDP         FDP       105 Days       FD       70004-0723-09       Kithadone       FDP         FDP       105 Days       70004-0380-05       Methadone 10 mg/mL 1 mL fill 3 mL Syringe       FDP         FDP       105 Days       70004-0300-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe       FDP         FDP       105 Days       70004-0100-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe       FDP         FDP       105 Days       70004-0100-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe       FDP         FDP       105 Days       70004-0100-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe       FDP         FDP       105 Days       70004-0100-16       Morphine 1 mg/mL in 0.9% Sodium Chloride 250 mL Bag       FDP         FDP       105 Days       70004-0100-16       Norepinephrine 4 mg in 0.9% Sodium Chloride 250 mL Bag       FDP

70004-0264-22	Fentanyl 2 mcg/mL + Ropivacaine 0.1% in 0.9% Sodium Chloride 50 mL fill 60 mL Syringe	FDP	105 Days
70004-0260-32	Fentanyl 2 mcg/mL + Ropivacaine 0.2% in 0.9% Sodium Chloride 100 mL Bag	FDP	105 Days
70004-0280-32	Fentanyl 2 mcg/mL and Ropivacaine HCl 0.2% in 0.9% Sodium Chloride 100 mL Bag	API	105 Days
	Hydromorphone		
70004-0300-18	Hydromorphone 0.2 mg/mL in 0.9% Sodium Chloride 30 mL Syringe	FDP	105 Days
70004-0300-16	Hydromorphone 0.2 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe	FDP	105 Days
70004-0300-30	Hydromorphone 0.2 mg/mL in 0.9% Sodium Chloride 50 mL Bag	FDP	105 Days
70004-0300-55	Hydromorphone 0.2 mg/mL in 0.9% Sodium Chloride 100 mL Bag	FDP	105 Days
70004-0303-17	Hydromorphone 1 mg/mL in 0.9% Sodium Chloride 25 mL fill 30 mL Syringe	FDP	105 Days
70004-0303-16	Hydromorphone 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe	FDP	105 Days
70004-0303-21	Hydromorphone 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 60 mL Syringe	FDP	105 Days
70004-0303-30	Hydromorphone 1 mg/mL in 0.9% Sodium Chloride 50 mL Bag	FDP	105 Days
70004-0300-22	Hydromorphone HCl 0.2 mg/mL in 0.9% Sodium Chloride 50 mL fill Syringe (10 mg/50 mL)	FDP	105 Days
	Ketamine		
70004-0435-09	Ketamine 10 mg/mL in 0.9% Sodium Chloride 5 mL fill 6 mL Syringe (50 mg/5 mL)	API	90 Days
70004-0435-12	Ketamine 10 mg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe (100 mg/ 10 mL)	API	90 Days
	Labetalol		

FDP

190 Days

70004-0700-28 Labetalol 5 mg/mL 4 mL fill 5 mL Syringe

### Product List

**Product Description** 

NDC



Product Source BUD

## Product List

NDC	Product Description	Product Source	BUD
	Rocuronium		
70004-850-09	Rocuronium 10 mg/mL 5 mL fill 6 mL Syringe	FDP	180 Days
70004-850-09-K	Rocuronium 10 mg/mL 5 mL fill 6 mL Syringe (Kit Check)	FDP	180 Days
70004-0850-12	Rocuronium 10 mg/mL 10 mL fill 12 mL Syringe	FDP	105 Days
70004-0850-12-K	Rocuronium 10 mg/mL 10 mL fill 12 mL Syringe (Kit Check)	FDP	105 Days
	Sodium Citrate		
70004-0900-25	Sodium Citrate 4% 3 mL fill 6 mL Syringe	FDP	105 Days
	Succinylcholine		
70004-0908-09	Succinylcholine 20 mg/mL 5 mL fill 6 mL Syringe	FDP	90 Days
70004-0908-09-K	Succinylcholine 20 mg/mL 5 mL fill 6 mL Syringe (Kit Check)	FDP	90 Days
70004-0908-12	Succinylcholine 20 mg/mL 10 mL fill 12 mL Syringe	FDP	90 Days
70004-0908-12-K	Succinylcholine 20 mg/mL 10 mL fill 12 mL Syringe (Kit Check)	FDP	90 Days
	Vancomycin (Refrigerated)		
70004-0920-59	Vancomycin 1 gram added to 0.9% Sodium Chloride 250 mL Bag	FDP	120 Days
70004-0923-59	Vancomycin 1.25 grams added to 0.9% Sodium Chloride 250 mL Bag	FDP	120 Days
70004-0924-59	Vancomycin 1.5 grams added to 0.9% Sodium Chloride 250 mL Bag	FDP	120 Days
70004-0924-44	Vancomycin 1.5 grams added to 0.9% Sodium Chloride 500 mL Bag	FDP	120 Days
70004-0926-44	Vancomycin 1.75 grams added to 0.9% Sodium Chloride 500 mL Bag	FDP	120 Days
70004-0928-44	Vancomycin 2 grams added to 0.9% Sodium Chloride 500 mL Bag	FDP	120 Days

	Phenylephrine		
70004-0811-12	Phenylephrine 40 mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe (400 mcg/10mL)	FDP	240 Days
70004-0811-12-K	Phenylephrine 40 mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe (400 mcg/10mL) (Kit Check)	FDP	240 Days
70004-0816-12	Phenylephrine 80 mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe	FDP	240 Days
70004-0816-12-K	Phenylephrine 80 mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe (Kit Check)	FDP	240 Days
70004-0810-11	Phenylephrine 100 mcg/mL in 0.9% Sodium Chloride 5 mL fill 12 mL Syringe	FDP	240 Days
70004-0810-11-K	K Phenylephrine 100 mcg/mL in 0.9% Sodium Chloride 5 mL fill 12 mL Syringe (Kit Check)		240 Days
70004-0810-12	Phenylephrine 100 mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe	FDP	240 Days
70004-0810-12-K	Phenylephrine 100 mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe (Kit Check)	FDP	240 Days
70004-0810-22	Phenylephrine 100 mcg/mL in 0.9% Sodium Chloride 50 mL fill 60 mL Syringe	FDP	240 Days
70004-0811-40	Phenylephrine 10 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	95 Days
70004-0808-40	Phenylephrine 20 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	95 Days
70004-0807-40	Phenylephrine 25 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	95 Days
70004-0825-40	Phenylephrine 40 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	95 Days
70004-0806-40	Phenylephrine 50 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	95 Days
70004-0805-40	Phenylephrine 100 mg in 0.9% Sodium Chloride 250 mL Bag	FDP	95 Days
	Potassium Chloride		
70004 0022 40	Patassium Chlorida 20 mEs added to 0.0% Sadium Chlorida 250 ml. Pas		00 Davis

70004-0832-40	Potassium Chloride 20 mEq added to 0.9% Sodium Chloride 250 mL Bag	FDP	90 Days
70004-0833-44	Potassium Chloride 40 mEq added to 0.9% Sodium Chloride 500 mL Bag	FDP	90 Days

#### **Potassium Phosphate**

70004-0841-40	Potassium Phosphate 15 mMol added to 0.9% Sodium Chloride 250 mL Bag	FDP	105 Days
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PF = Preservative Free BUD is from the date of product compounding

Product catalog is subject to change. Visit SCA's eCommerce portal or contact your Regional Sales Director with any questions.



### End Product Testing

To guarantee product quality and safety, each batch is tested against rigorous specification criteria prior to release. SCA Pharma's End Product Testing protocol covers five major components and includes the generation and approval of a Certificate of Conformance (C of C) by Quality Assurance.

C of C acceptance criteria and test results become part of the completed batch record and can be viewed via our eCommerce Portal.

**End Product Testing components:** 

### **Defect-Free**

All sterile products must be free of critical/major defects prior to release. Skilled operators inspect 100% of units and an AQL level is independently verified.

#### **Environmental Monitoring**

Comprehensive environmental monitoring is performed during compounding per USP <1116> and cGMP.

#### **Endotoxin Limits**

All sterile products must pass applicable standards for endotoxin (pyrogen) limits. Test methods have been validated per USP <85> and cGMP guidelines.

### **Sterility Testing**

Scan RDI (Rapid Microbiological Technology) enables quick turnaround time for sterility testing of sterile products which maximizes usable shelf life. Scan RDI usage has been gualified to be equivalent to or better than USP <71> traditional sterility methods.

#### **Potency/Identity Specifications**

Scientifically sound and appropriate specifications have been established for all products. Every log is tested for both strength (potency) and identity by methods which are highly specific.

### SCA Pharma's Commitment to Quality

Delivering the highest quality medications to our partners and their patients is SCA Pharma's top priority. Our comprehensive training and personnel qualification criteria ensure full compliance with regulatory requirements on every batch we produce.

## Contact Us

