## CP2D- cp2d solution GVS TM INC

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#### **CP2D listing**



# ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION (CP2D), 250 mL

Intended for use only with automated red cell apheresis devices to collect red blood cells and plasma (FFP and PF24). See the appropriate Operator's Manual for additional information and complete usage instructions.

Each 100 mL contains:

Citric Acid (Monohydrate), USP	0.327 g
Sodium Citrate (Dihydrate), USP	2.630 g
Monobasic Sodium Phosphate (Monohydrate), USP	0.222 g
Dextrose (Anhydrous), USP	4.640 g

**CAUTION:** Refer to package insert. Not for direct intravenous infusion. The pouch is a moisture barrier.

Do not use unless solution is clear and no leaks detected.

Single use container. Discard unused portion.

Sterile, nonpyrogenic fluid path. Sterilized by steam. Rx Only.

Store at room temperature (25 °C/77 °F). Avoid excessive heat. Protect from freezing.

REF

0455A-00

LOT

126616-00 REV.0



to collect red blood cells and plasma (FFP and PF24).

#### Storage and handling section



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#### Warnings and precautions



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Warnings

Not for direct intravenous infusion.

Single-use container - discard unused portion. (do not reuse)

Do not use unless the solution is clear and no leaks are detected.

**Precautions** 

Use only with automated red-cell apheresis devices and follow the Operator's Manual.

Refer to the package insert for complete instructions.

Storage/handling: Store at 25 °C/77 °F, avoid excessive heat, protect from freezing.

Pouch is a moisture barrier; handle to maintain package integrity.

#### **Description section**



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ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION (CP2D), 250 mL 0455A-00

Statement of identity



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#### 126616-00 REV.0



Manufacturer information: GVS TM Inc. 1630 W Industrial Park St Covina, CA 91722, USA

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lot and expiry date

126616-00 REV.0 - template number

#### CP2D

cp2d solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:87069-455
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE, UNSPECIFIED FORM	4.64 g in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
MONOBASIC POTASSIUM PHOSPHATE (UNII: 4J9FJ0HL51)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87069-455- 42	24 in 1 CARTON		
1	NDC:87069-455- 02	250 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN820915	09/30/2025	

### **Labeler -** GVS TM INC (119067149)

### Registrant - GVS TM INC (119067149)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
GVS TM INC		119067149	manufacture(87069-455)	

Revised: 9/2025 GVS TM INC