

Somerset Iherapeutics LLC

Preservative free.

10,000 mg per 100 mL (100 mg per mL)
PHARMACY BULK PACKAGE - NOT FOR DIRECT INFUSION

Calcium Gluconate Injection, USP

NDC 70069-**728**-10

Rx only

ST-CLG13-MPPL/C10/00

Sterile

Each mL contains: Calcium gluconate 94 mg; calcium saccharate (tetrahydrate) 4.5 mg; water for injection, q.s. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment.

0.465 mEg/mL 276 m0smol/L

Contains no more than 512 mcg/L of aluminum.

Preparation of Pharmacy Bulk Package:

This pharmacy bulk package (PBP) is intended for dispensing of single doses to multiple patients in a pharmacy admixture program. Penetrate the container closure only one time with a suitable sterile transfer device or dispensing set that allows measured dispensing of the contents.

Use the PBP only in a suitable ISO Class 5 work area such as a laminar flow hood (or an equivalent clean air compounding area). Complete dispensing from the pharmacy bulk package vial within **4 hours** after the container closure is penetrated.

Dispensed aliquots must be used immediately and cannot be stored. See insert for further details.

Supersaturated solutions are prone to precipitation. See insert for further details.

STORE AT: 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not freeze. Use only if solution is clear and seal intact. The container closure is not made with natural rubber latex.

Manufactured for:

Somerset Therapeutics, LLC Hollywood, FL 33024 Customer Care # 1-800-417-9175

Made in India Code No: TN00006382

1200780

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Somerset ::::
Therapeutics LLC

US/094/CA/094 V01 PCT324

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105 x 60 mm

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Keep area blank and varnish free for overprinting LOT and EXP

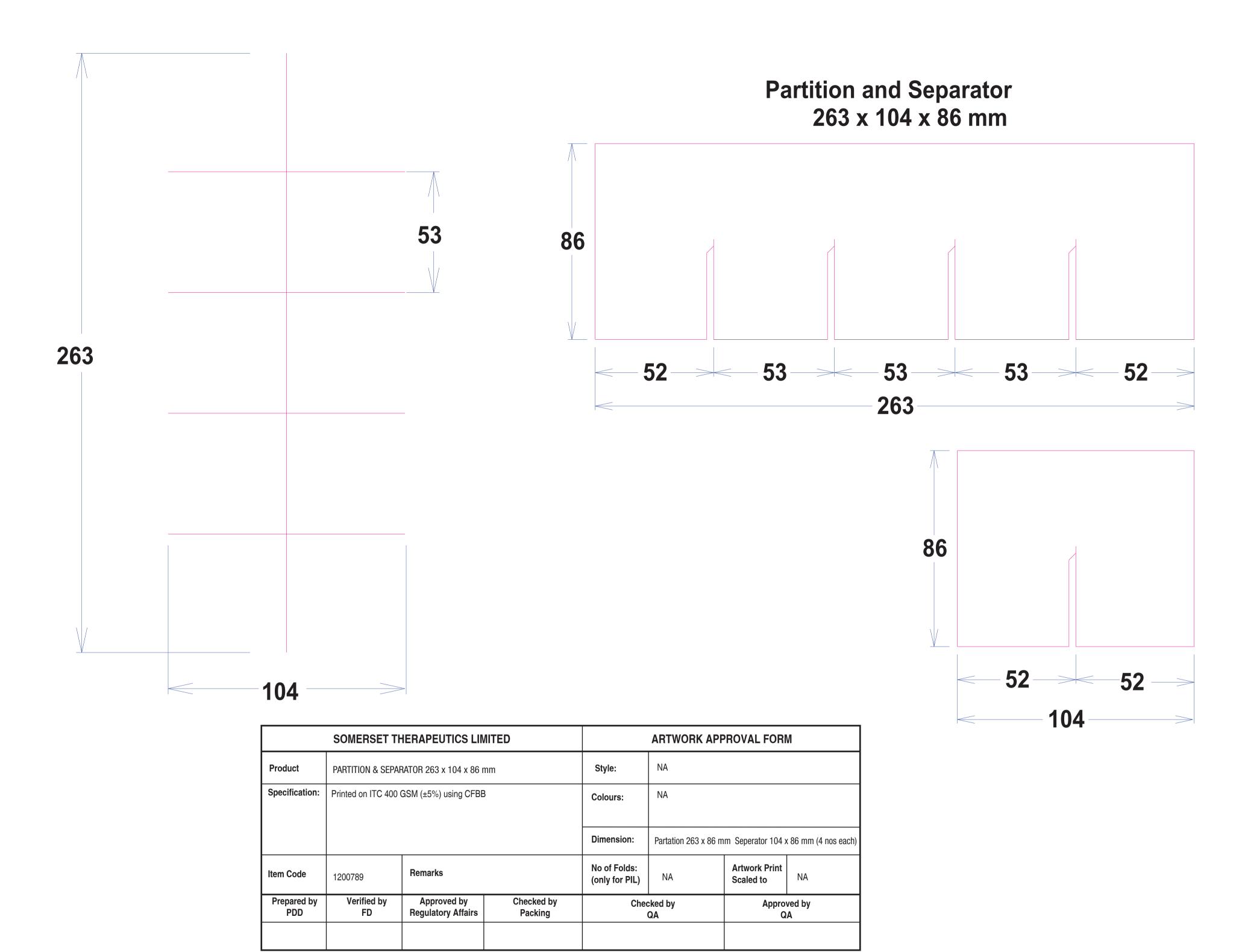
ARTWORK APPROVAL FORM **SOMERSET THERAPEUTICS LIMITED** Calcium Gluconate Injection USP, 10000 mg/100 mL (100 mL Carton) Style: **Product** Lock Bottom Specification: Printed on ITC 400 GSM (±5%) using CFBB P 2356 C P 300 C Colours: with Siegwerk India aqueous varnish (benzophenone free) Black C P 032 Red C Ink: Siegwerk / DIC India (benzophenone free) 265 x 106 x 106 mm (LxWxH) Dimension: No of Folds: **Artwork Print** Remarks Item Code 1200780 (only for PIL) Scaled to Verified by Checked by Prepared by Approved by Checked by Approved by **Regulatory Affairs Packing**

DOES NOT PRINT



ie Line





F-RAA-002-02