



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

Introduction Type: New Item

Final Version

Date:

| PRODUCT INFORMATION | | SPECIAL HANDLING AND STORAGE REQUIREMENTS* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------------|--|----------------|--------------------------|-------------------|------------------------|-------------------|---------------------|---|-------------------|-------|----------------|--------------|--|-------|----|------|-----|--|---------------------|-------|----------------|----|--|----|---------|----|---------|-----|------|-----|-----|--------|---------------------|--|-----|----|----|----|-------|---------------------|--|--|
| Company Name: CREEKWOOD PHARMACEUTICALS LLC Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 204989 Medical Device Class, if applicable: _____ DUNS: 118582565 Proprietary Name (If Applicable) and Established Name: Gabapentin capsules, USP 300 mg .500's per Bottle Selling Unit NDC: 82619-143-02 Unit of Use NDC: 82619-143-02 UPC: N382619143027 UDI: NA CVX Code: _____ MX Code: NA Description: White to off white powder filled in size "1" hard gelatin capsules with opaque Yellow colored cap and opaque Yellow colored body imprinted "SG" on cap and "180" on body with black ink Active Ingredient(s): Gabapentin URL for Additional Product Information: _____ Address: 1130 US 46 W Address 2: Suite 21 City: Parsippany State: NJ Zip: 07054 Key Contact: Paul Thomas Email: paul@creekwoodpharma.com Phone Number: 1-732-344-022 Fax: _____ Product Therapeutic Classification: Anticonvulsant | | a. Temperature – Indicate the USP temperature range for this product. Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in): _____ Notes: _____ Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No b. Contact for temperature excursion questions: Name: SUJIT SAKPAL Number: 551-303-9330 Group E-mail: sujit@creekwoodpharma.com c. Special regulations for product in any states? <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No d. Store product (unit of sale) upright? <input type="checkbox"/> Yes Protect product (unit of sale) from light? <input type="checkbox"/> No e. Shelf life: Initial shelf life at launch (if different): _____ Months <input type="text" value="36"/> Months | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| The product is? a legend device? <input type="checkbox"/> No if yes, enter class # _____ a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? _____ co-licensed? <input type="checkbox"/> No latex-free? <input type="checkbox"/> Yes preservative-free? <input type="checkbox"/> Yes correctional institution block? <input type="checkbox"/> No opioid? <input type="checkbox"/> No Cannabinoid? <input type="checkbox"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No If Unit Dose, indicate NDC here: _____ | | Is the Product... Direct-Ship Only <input type="checkbox"/> Is the Product... Unit of Use _____ Orphan Drug Status _____ FDA Approval Status _____ Allergens Present _____ Country of Origin INDIA Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | Size: 19mm -Size '1' Strength: 300 mg Dosage Form: capsule Product Shape: CAPSULE Product Color: Yellow color cap/Yellow color body Product Imprint: SG on Cap and 180 on Body | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| FOR GENERIC DRUG PRODUCTS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| I. Orange Book Rating: _____ <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: Neurontin (gabapentin) Capsules | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Does supplier meet DSCSA definition of manufacturer? <input checked="" type="checkbox"/> Yes GLN: 850045940003 Is product exempt from DSCSA? <input type="checkbox"/> No If yes, select exemption: _____ Other exemption - Write in: _____ Is product repackaged? <input type="checkbox"/> No GCP: 850045940 Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No Has FDA granted waiver/exemption/exemption for product? <input type="checkbox"/> No If yes, attach documentation from FDA. _____ If yes, was original product purchased direct from mfr? <input type="checkbox"/> No Provide source manufacturer for repackaged product _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| GTIN AND HIBCC PRODUCT INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Saleable Unit of Measure</th> <th>Saleable Quantity</th> <th>HIBCC</th> <th>GTIN-14</th> <th>Unit of Use GTIN-14</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Item/Each</td> <td>500</td> <td></td> <td>00382619143027</td> <td>382619143027</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> Case</td> <td>12</td> <td></td> <td>20382619143021</td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> Pallet</td> <td>1</td> <td></td> <td></td> <td></td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> | | | | Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 | <input checked="" type="checkbox"/> Item/Each | 500 | | 00382619143027 | 382619143027 | <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | | | | | <input checked="" type="checkbox"/> Case | 12 | | 20382619143021 | | <input checked="" type="checkbox"/> Pallet | 1 | | | | | | | | | | | | | | | | | | |
| Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Item/Each | 500 | | 00382619143027 | 382619143027 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Case | 12 | | 20382619143021 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Pallet | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ORDER INFORMATION | | PHARMACY ORDER / BILL UNIT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Powder Multi <input type="checkbox"/> Other: Write In _____ | | What is the NDC selling unit? 1 Bottle of 500 Capsules (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? <input checked="" type="checkbox"/> Each <input type="checkbox"/> Inner/Carton/Pack <input type="checkbox"/> Case | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Rec. sell unit to customer? <input type="text" value="Bottle"/> (Write-in, e.g. 1 Vial) | | Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ITEM AND PACKING INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Item/Each:</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2">Saleable # Pieces</th> </tr> <tr> <th>Depth</th> <th>Width</th> <th>Height</th> </tr> </thead> <tbody> <tr> <td>Box/Carton/Bundle/Inner Pack:</td> <td>0.594</td> <td>NA</td> <td>5.71</td> <td>3.1</td> <td>#VALUE!</td> <td>500 Caps per Bottle</td> </tr> <tr> <td>Case:</td> <td>NA</td> <td>NA</td> <td>NA</td> <td>NA</td> <td>#VALUE!</td> <td>NA</td> </tr> <tr> <td>Pallet:</td> <td>7.8</td> <td>12.6</td> <td>7.8</td> <td>9.5</td> <td>933.66</td> <td>12 Bottles per case</td> </tr> <tr> <td></td> <td>700</td> <td>48</td> <td>48</td> <td>40</td> <td>92160</td> <td>84 cases per Pallet</td> </tr> </tbody> </table> | | | | Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | Saleable # Pieces | Depth | Width | Height | Box/Carton/Bundle/Inner Pack: | 0.594 | NA | 5.71 | 3.1 | #VALUE! | 500 Caps per Bottle | Case: | NA | NA | NA | NA | #VALUE! | NA | Pallet: | 7.8 | 12.6 | 7.8 | 9.5 | 933.66 | 12 Bottles per case | | 700 | 48 | 48 | 40 | 92160 | 84 cases per Pallet | | |
| Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | | Volume (Cube) | Saleable # Pieces | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | Depth | Width | Height | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Box/Carton/Bundle/Inner Pack: | 0.594 | NA | 5.71 | 3.1 | #VALUE! | 500 Caps per Bottle | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Case: | NA | NA | NA | NA | #VALUE! | NA | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pallet: | 7.8 | 12.6 | 7.8 | 9.5 | 933.66 | 12 Bottles per case | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 700 | 48 | 48 | 40 | 92160 | 84 cases per Pallet | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| COST INFORMATION | | WHOLESALE USE ONLY: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Regular Cost _____ Invoice Cost (WAC) (\$) _____ As of date: _____ | | Vendor #: _____ Whsl. Code #: _____ Fineline Code: _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION | | | | | | | |
|--|--|----------------------------------|------------------------------------|------------------------------------|-----------------------------------|---|---|
| <p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? <input type="checkbox"/> No (If yes, attach SDS with special instructions.)</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p> | <div style="background-color: #002060; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="checkbox"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> | <input type="checkbox"/> Organic | <input type="checkbox"/> Corrosive | <input type="checkbox"/> Inorganic | <input type="checkbox"/> Oxidizer | <input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Contact Hazard |
| <input type="checkbox"/> Organic | <input type="checkbox"/> Corrosive | | | | | | |
| <input type="checkbox"/> Inorganic | <input type="checkbox"/> Oxidizer | | | | | | |
| <input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Contact Hazard | | | | | | |
| Hazardous Waste Identification | | | | | | | |
| EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/> | | | | | | | |
| REMS or REGISTRY RESTRICTIONS | | | | | | | |
| <p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry? <input type="text"/></p> <p>Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/> No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/> No</p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/> IT IS NOT A REMS PRODUCT</p> <p>Registry:</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/> IT IS NOT A REMS PRODUCT</p> | | | | | | | |
| ADD'L STORAGE INFORMATION | | | | | | | |
| <p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No Listed Chemical (List I or II) <input type="text"/> <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product? <input type="checkbox"/> No</p> | | | | | | | |
| CLASS OF TRADE RESTRICTION: | | | | | | | |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p> | | | | | | | |
| RETURN INSTRUCTIONS | | | | | | | |
| <p>Contact tel. # if product received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf</p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> | | | | | | | |
| MISCELLANEOUS NOTES and/or Image of Product Barcode: | | | | | | | |
| <input type="text"/> | | | | | | | |



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

| Order Method for Designated Drop Ship Product | Standard Order Receipt and Processing |
|---|---|
| Purchase orders may be accepted by: a. EDI <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Units Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Direct customer solutions (R & S) Phone: <input type="text"/> 1-800-655-7556 Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/> | Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/> | Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="text"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/> |
| Class of Trade Restriction: | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/> | |
| Other Data Information Required to Process PO: | Return Instructions |
| Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/> | Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/> |
| Miscellaneous Notes: | |
| <input type="text"/> | |
| | ADDITIONAL INFORMATION |
| | Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/> |