Sent by: Medlsca Alex

Sent to:

CC:

Bcc:

Subject: [Monitor] RE: Re: RE: RE: RE: Medisca Inc. // Product Inquiry// Medroxyproges throne USP/EP

Date: 2019-03-21 21:46:51

Attachment: med\_885f6950-e6e4-44d9-8eb7-0ca3c7d3f082.jpg (3.0K) MEDISCAgreenleaf\_flffa052-bd06-4189-b9a5-9f3da9d7cf6e.png (844.0B)

Hi Cherry!

Nice and fresh! :) Please ship at your earliest convenience.

Thanks and wishing you a nice evening

Alex

**Alex Normand**

**Acheteur/Buyer**

ANormand@medisca.com

From:——

Sent: Wednesday, March 20, 2019 9:16 PM

To: Alex Normand <ANormand@medisca.com>

Subject: Fw: Re: RE: RE: RE: Medisca Inc. // Product Inquiry// Medroxyproges throne USP/EP

Dear Alex,

Please check the COA in the annex and confirm if it is ok.

Best regards!

Cherry

——————

**Taifa Pharma**

**Product Release Review / Approval Form**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Product Name | Medroxyprogesterone acetatea | Code | 5055 | Package Standard | 25kg/barrel |
| Serial No. | 5035-181002 | Quantity | 50kg | Product Inspection Proof | VSP38/EP8.0 |
| No. | Reviewed Item | Standard | Result |
| 1 | Whether production workshop, production dept and central testing room is reviewed | Meets requirements and confirm with signature | ✔️ |
| 2 | Raw and supplement material, packaging material and media | Has certificate of conformity | ✔️ |
| 3 | Production process | Meets procedure requirements, implemented standard operation procedures, each procedure’s production record contains operator and validator’s signature | ✔️ |
| 4 | Serial production record, packaging record, inspection record | Key data in the records aren’t written over or modified, if modified, reasonable cause is stated; Effective digital rounding matches, binding is complete | ✔️ |
| 5 | Production deadline | This round of product’s completion date is within the serial production order deadline | ✔️ |
| 6 | Material balance inspection | Each procedure’s material balance meets required limit | ✔️ |
| 7 | Production error | Strictly follows error process procedure, processing procedure is correct with no mistakes and can ensure product quality. | ✔️ |
| 8 | Sampling record | Sampling record is clear and complete, without significant situations affecting sample quality | ✔️ |
| 9 | Inspection procedure | Meets quality standard requirement, implements standard operation procedure, each item record contains operator and validator’s signature | ✔️ |
| 10 | Whether measuring tools are within the lifespan | Has certificate of conformity | ✔️ |
| 11 | Standard product | Within lifespan | ✔️ |
| 12 | 00S | Strictly implements OOS processing program, processing procedures are accurate and flawless | ✔️ |
| 13 | Data Unity | Inspection record matches data in the report sheet | ✔️ |
| 14 | Misc. | Meets requirements | ✔️ |
| QA: Date: 03/20/2014 |
| Conclusion | After review, this round of product is considered **Qualified product, approved to move on.** Unqualified product, not approved to leave factory Doesn’t meet review standards, not approved to leave factoryReason of disapproval:Suggested responses:Final Reviewer: Yuan Weiqing Date:03/20/2019 |

Note: If review results meets requirements, mark with “✔️” in the result column; if not, mark with “x”

|  |  |  |  |
| --- | --- | --- | --- |
| Code: | BPR-2004-1.2 | Confidential Grade: |  **Secret** confidential top-secret |
| Title: | BPR for Package Job Operation |
| Drafted by:  | Wu Junliang | Date: 04/01/2014 | Drafting Dept: Production |
| Reviewed by:  | Zhang Taihai | Date: 04/02/2014 | Issued by: QA |
| Reviewed by QA:  | Wang Weizhong | Date: 04/03/2014 | Effective Date: 07/01/2014 |
| Approved by： | Wang Haiqing | Date: 04/04/2014 | Reviewed Date: 06/2019 |
| Yuan Weiqing | Date: 04/06/2014 |

Product Name Medroxyprogesterone acetatea

Code 5035

Serial Number 5035-181002

Inventory Amount 58.56 kg

Production Date 03/20/2019 - 03/20/2019

Workshop Review Wu Junliang 03/20/2019

Production Review Zhang Taihai 03/20/2019

QA Review Wang Weizhong 03/20/2019

Taizhou Taifa Pharmaceuticals Co.Ltd.

Pulverizing, Blending and Packaging Instruction Order

|  |  |  |
| --- | --- | --- |
| Type | Mixed. **Packaged**. Separate Container | Crushed. Machine-crushed \_\_\_ times Airflow-crushed \_\_\_\_\_ times |
| Product Name | Medroxyprogesterone acetatea | Serial No. | 5035-181002 |
| Quantity | 50kg | Operation Date | 03/20/2019 |
| Operation Standard | TF/5-3023-2,0 |
| Name of the product awaiting crushing/mixing/packaging | Serial No. | Inspection Ticket No. | Workshop | Quality Standard | Quantity (kg) |
| Medroxyprogesterone acetatea | 5035-181002 | B-1903003 | C101 | USP37 | 58.565 |
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| Package Material Name | Serial No. | Inspection Ticket No. | Producer | Dimensions | Quantity |
| Plastic Bag | 2015-1703001 | C-1703010 | - | 1100\*720\*0.1mm | 4 |
| Cardboard Barrel | 2032-1807001 | C-1807003 | - | 450\*750 | 2 |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Note: 25kg/barrel |
| Ticket creator/date:Hang Junsheng03/20/2019 | QA reviewer/date:Wang Weike03/20/2019 | Technical reviewer/date:Zhang Taihai03/20/2019 | Approved by/date:Wu Junliang03/20/2019 |

**General Guideline**

1. Before production, must first examine whether labor protective equipment is worn.
2. Before production, must first examine whether raw materials and medium materials have testing certificate of conformity, testing ticket and check-out ticket serial number, whether quantities match and whether the physical appearance is normal.
3. Before production, must first examine whether all supplemental materials have certificate of conformity, whether appearance and scent is normal, and whether quantities are sufficient.
4. Before production, must examine whether water, electricity, steam, freezing and vacuum is normal, and whether equipment operation is normal.
5. Producers must follow the safety guideline used as reference in the serial record, and must use the local exhaust following the requirements when operating all processing procedures.
6. Containments and barrels sent to the production district must be sanitary.
7. Confirmation reaction equipment must be sanitary before production.
8. After production, put the products into appropriate containers, fill out the labels and paste them on the containers.
9. All equipment must be clearly labeled.
10. Maintain production district sanitation.

**Table of Content**

**I. Inner Package**

**II. Outside Package**

|  |  |  |  |
| --- | --- | --- | --- |
| Drafter | Wu Junliang 04/01/2014 | Reviewer | Zhang Taihai 04/02/2014 |
| Approved by | Wang Haiqing 04/04/2014 | Approved by | Yuan Weiqing 04/06/2014 |

|  |  |  |  |
| --- | --- | --- | --- |
| Product Name | Medroxyprogesterone acetatea | Serial No. | 5035-181002 |
| (Inner Package) I. Pre-production preparation and inspection confirmation |
| Inspection Confirmation | Before production, follow the requirements in TF/5-0009 “Pre-production Preparation and Inspection Confirmation Operation Procedure” and conduct inspection confirmation1. Inspect to confirm the sufficiency of production orders, relevant procedure and records (serial record, supplement record), preparation and procedure learning and training.
2. Confirm production work space (ceiling, wall surface, door and window, floor) is sanitary without product, document, labels left from last round of production or
3. Material unrelated to this round of products, and confirm that humidity and temperature meets process requirements.
4. Confirm that facilities, containers and tools are competent without damage, sanitary status matches process requirement. Confirm that facilities “ON/OFF” status are accurate without errors.
5. Confirm normal energy supply is normal, or valve “ON/OFF” status is accurate without errors.
6. Inspect to confirm measurement machinery and meters (scale, thermostat (thermometer), pressure gauge, vacuum gauge) are complete without damage and are within the conformity validation cycle.
7. Check-out and validation (product name, standards, serial no, quantity, etc) of products awaiting to be crushed.
8. Confirm labor insurance measures, contamination-prevention measures, safety production measures (work uniform, mask, etc) and others are worn properly.

Confirmed by: Wang Haiyan Date: 03/20/2019 Validated by: Chen Qingyang Date: 03/20/2019 |
| II. Materials awaiting packaging |
| Product Name | Serial No. | Checked-out Quantity (kg) | Production Date | Validation Date | Operator/Date | Validator/Date |
| Medroxyprogesterone acetatea | 5035-181002 | 58.565 | 09/04/2018 | 09/03/2021 | Wang Haiyan03/20/2019 | Chen Qingyang03/20/2019 |
| III. Package Materials |
| Name | Serial No. | Checked-out Quantity (kg) | Remaining Quantity | Operator/Date | Validator/Date |
| Plastic Packaging Bag | 2015-1703001 | 4 | 0 | Wang Haiyan03/20/2019 | Chen Qingyang03/20/2019 |
| Nylon Ties | - | 4 | 0 |
| Aluminum Can | - | - | - |
| Foil bag | - | - | - |
| Label/Marks | - | - | - |
| IV. Inner Package (Operation Unit 4) Production Operation Procedure |
| Operation Procedure Details | Index and records | Operator/Date | Validator/Date |
| 1. Validate serial number and weight of the product awaiting packaging, exchange to status labels.
2. Check-out needed packaging material and label. Validate that labels are complete without damage.
3. Disinfect packaging materials for 15min through transfer window before transporting to inner workshop. Inspect plastic bags to confirm their competency, after cleaning, weigh the double-layer plastic bags according to packaging requirements, and reset the electronic scale. If aluminum can packaging is needed, remove outer packaging of the aluminum cans, and inspect whether pollutants are present in and outside the aluminum can. Move from material logistics buffer room to inner-packaging room only after confirming cleaning and disinfection. Insert inspected double-layer plastic bags into the aluminum cans and weigh with the aluminum can. Reset electronic scale.
4. Take out material with specified spoon and put into weighed and reset double-layer plastic bags.
5. Weigh according to packaging standards: Tare + Packaging dimension quantity.
6. After the validator validates measurement number is without errors, from inside to outside, use one-time ties to tie double-layer plastic bags respectively, and use one-time ties to tie-up remaining materials.
7. Use clean rag gently wipe off medicine powder on the packaged plastic bag or aluminum can. Neatly paste label onto the plastic bag or aluminum can.
 | Labels complete: **Y**/NPackaging materials complete: **Y**/NInner package time: 09:10 to 09:35Packaged pieces: 2pcsA Package Quantity: 50.00kgB Remaining: 8.56kgC Reusable material: - kgD Sample quantity: - kg | Wang Haiyan03/20/2019 | Chen Qingyang03/20/2019 |
| Material Balance = | A+B+C+D | x 100% = | 50.00+8.56 | x 100% = 99.99% | Material balance permission 98.0-100.0% |
| Pre-crushing quantity | 58.565 | Conclusion: **Approved**Not Approved |
| Workshop Inspection FeedbackNormalInspector: Wu JunliangDate: 03/20/2019 | QA Inspection FeedbackNormalInspector: Zhang Ke03/20/2019 |
| Drafter | Wu Junliang 04/01/2014 | Validator | Zhang Taihai 04/02/2014 |
| Approved by | Wang Haiqing 04/04/2014 | Approved by | Yuan Weiqing 04/06/2014 |

|  |  |  |  |
| --- | --- | --- | --- |
| Product Name | Medroxyprogesterone acetatea | Serial No. | 5035-181002 |
| (Outer Package) I. Materials waiting packaging |
| Product Name | Serial No. | Inner packaging piece count | Quantity (kg) | Remaining pieces | Quantity(kg) | Operator/Date | Validator/Date |
| Medroxyprogesterone acetatea | 5035-181002 | 2- | 50.00 | 1 | 8.56 | Wnag Haiyan 03/20/2019 | Chen Qingyang03/20/2019 |
| II. Packaging Material |
| Product Name | Serial No. | Checked-out Quantity (kg) | Used Quantity | Remaining Quantity | Operator/Date | Validator/Date |
| Cardbox | Inner box | / | / | / | / | Wang Haiyan03/20/2019 | Chen Qingyang03/20/2019 |
| Outer box | / | / | / | / |
| Card Barrel | 2032-1807001 | 2 | 2 | 0 |
| Plastic Barrel | / | / | / | / |
| Insert | / | 2 | 2 | 0 |
| Label/Marks | / | 2+2 | 2+2 | 0 |
| III. Outer Package (Operation Unit 5) Production Operation Procedure |
| Operation Procedure Details | Index and records | Operator/Date | Validator/Date |
| 1. Send packaged material from Buffer Room or Transportation Window to Outer Package Room, and insert into outer package barrel or carton box: close the package barrel lid, insert a lock with Tai Fa company name printed upon, and wrap barrel lid ring with tapes printed with Tai Fa company name for one week or more. Alternatively, close carton box lid, and seal the box with tapes printed with Tai Fa company name.
2. Clean and sanitize finished outer-package barrel or carton box, validate label content, confirm that there are no errors and neatly paste label on the outer-package barrel or carton box.
3. Process storage. Warehouse storage personnel re-weigh and validate the gross weight of each barrel or box, and record weighed piece counts; after passing the inspection, complete inventory.
 | Outer packaging time: 09:35 - 09:55 | Wang Haiyan03/20/2019 | Chen Qingyang03/20/2019 |
| Package Count: 2pcsPackage Quantity: 50.00 kgRemaining: 1pcRemaining Quantity: 8.56 kgPackaged product sum: 58.56 kg |
| IV. Post-production Field Cleaning |
| Inspection and Confirmation | After completing each operation unit, follow requirements in TF/5-0010 “Production Field Cleaning Management Procedure” to clean the field.1. Production residues of this round (material, product, document) are cleaned up.
2. Confirm that equipment, measurement equipment, production tool and equipment is all cleaned according to individual cleaning operation standard, and is stored accordingly at designated location.
3. Confirm that production location (operation platform, ceilings, walls, doors and windows, floor, etc.) are cleaned according to required procedures.
4. Packaged products are stored into the warehouse.
5. Cleaning tolls are cleaned and stored to designated location.
6. The “cleaned” status label is prepared.

Cleaner: Wang Haiyan, 03/20/2019Validator: Chen Qingyang, 03/20/2019 |
| V. Abnormalities and Errors |
| Abnormalities and Error Results: **None** YesDescription:Recorded by: Wang HaiyanDate: 03/20/2019 |
| VI. Workshop Manager, QA Official Review |
| Review feedback: NormalReviewer: Wu JunliangDate: 03/20/2019 |
| VII. QA Review |
| Review feedback: NormalReviewer: Zhang KeDate: 03/20/2019 |
| Drafter |  | Wu Junliang 04/01/2014 | Validator | Zhang Taihai 04/02/2014 |
| Approved by |  | Wang Haiqing 04/04/2014 | Approved by | Yuan Weiqing 04/06/2014 |

**Packaging Standard**

|  |  |
| --- | --- |
| Standards | Numbers |
| 1kg/can | 1 can/box, \_\_\_\_ boxes, total \_\_\_\_ kg |
| 2 can/box, \_\_\_\_ boxes, total \_\_\_\_ kg |
| 4 can/box, \_\_\_\_ boxes, total \_\_\_\_ kg |
| 5 can/box, \_\_\_\_ boxes, total \_\_\_\_ kg |
| 10 can/box, \_\_\_\_ boxes, total \_\_\_\_ kg |
| 5kg/can | 1 can/box, \_\_\_\_ boxes, total \_\_\_\_ kg |
| 2 can/box, \_\_\_\_ boxes, total \_\_\_\_ kg |
| 10kg/can | 1 can/box, \_\_\_\_ boxes, total \_\_\_\_ kg |
| **25kg/barrel** |  2 barrels, total 50.0 kg |
| 2kg/foil bag | Pack 5 bags into one package, then put into barrels. \_\_\_\_ barrels, total \_\_\_ kg |

 Note: 1. Remainders are packaged according to client requirements

 Package standard: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Total: \_\_\_ pcs \_\_\_ kg

 2. Remainders from round of packaging are put into cardboard barrels and added to inventory

 Package standard: 8.56kg/barrel x 1 barrel

 Total: 1 pc 8.56 kg

**Inner-Package Weighing Record**

Page 1 Total 1 Page

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No. | Gross Weight kg | Net Weight kg | Operator/Date | Validator/Date |
| 1 | 0.320 | 25.000 | Wang Haiyan03/20/2019 | Chen Qingyang03/20/2019 |
| 2 | 0.320 | 25.000 |
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| Notes | / |

**Produce, Verify and Paste of Production Mark Record**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Order Info | Client Name | 00000 41 | Shipping Date | 03/20/2019 |
| Product Name | Medroxyprogesterone acetatea | Serial No. 15035-181002 | Version: usp38/EP8 |
| Shipment number/kg | 50kg | Package Standard | 25kg/barrel |
| Mark Creation | Reviewed Item | Review Result |
| Whether mark sample’s text, image and logo is correct | **YES** NO |
| Whether the shipped finished product info provided by finished product warehouse manager is in line with shipping report | **YES** NO |
| Whether the digital mark is in line with the A4-printed mark | **YES** NO |
| Mark Maker | Zheng Qian03/20/2019 | Numbers made/pcs | 4 Zhang Ke 03/20/2019 |
| Mark Pasting | Reviewed Item | Review Result |
| Whether mark info (limited to product name, version, serial no, serial quantity, production date) is in line with the actual product and package’s info. | **YES** NO |
| Whether mark count 4 counted by Zhang Ke is in line with print count and the number awaiting pasting | **YES** NO |
| Whether individually pasted product mark over finished product label matching the actual product | **YES** NO |
| If outer-package has finished product label, is the info in line with mark info (limited to product name, version, serial no, serial quantity, production date) | Finished Product Label **YES**  NOConformity **YES** NO |
|  | Mark balance calculation, check-out number 4 = used number 4 + remainder 0  | **YES** NO |
|  | Whether mark was damaged during pasting | YES, re-printed \_\_\_ pcs**NO** |
|  | Mark Paster | Chen Qingyang03/20/2019 | QA | Zhang Ke 03/20/2019 |
| Notes | Attachment (A4 printed version mark, mark sample) |
|  |