Central Administration of Drug Control
General Administration of Evaluation and Control

Notice to Applicant

Requirements for submitting samples to the General Administration of Evaluation and Control 2024

Code: EDREX:NP. CADC .010
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Effective date: 07/07/2024

Samples submission requirements for the Administration of Evaluation and Approval

1-Documents required to be submitted to the administration of Evaluation and Approval:

1.1 Fulfillment e mail

- A copy of the fulfillment e mail sent by the administration
- Reg.nodcar@gmail.com

1.2 Original copy of samples withdrawal form (Ornik)

To Assure the following:

- Sample's name
- Sample's production and expiry date
- Owner's name
- Factory name
- Pharmaceutical form
- Withdrawal reason
- Withdrawal type
- Variation samples, if any, which must be recorded in the withdrawal report
- Number of delivered samples are identical to the seized samples and that is recorded in the withdrawal form
- In case of incorrect or modified data the inspector will sign and stamp it
- If the date of issuing withdrawal form is different from the date of issuing withdrawal report, A technical report should be submitted including the reason of reissuance.

1.3 Withdrawal record

- A copy of withdrawal record
- Record any variations in the manufacturing conditions in the record
- Sample's name, batch no., country of origin and raw material suppliers should be identical to that submitted with the sample's file for assessment

1.4 Column Commitment

- The Commitment form is printed on a document bearing the company logo with original stamp .
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1.5 Attachment receipt

- To view the attachment to be submitted to the Evaluation and Approval Administration, please click on the link below:
- **Attachments receipt**

1.6 Registration form

- To view the attachment to be submitted to the Evaluation and Approval Administration, please click on the link below:
  - https://www.edaegypt.gov.eg/media/cudhgw3f/registeration-form.pdf

1.7 payment receipt

- Original cash receipt showing the name of the product sample and not subject to deletion or modification/ automated payment slip
- Original payment of full analysis fees including Hazardous or excipients if any
- A copy of the impurity analysis fees receipt

2. Analysis requirements

2.1 Reference Standards requirements:

2.1.1 Reference standard (USP-BP-EDQM)

- Delivered in the original, tightly sealed package
- Current Batch
- Matched with what has been fulfilled
- Stored under proper storage conditions.
- Attaching the certificate that containing potency, especially in the case of an EDQM standard substance

2.1.2 Working standard

- Delivering sufficient amount for analysis
- Supplier certificates
- Original copy of traceability certificates original Signatures and stamp .

2.1.3 White List Standard

- Ensure that the material is included in the white list
- Attach the sample certificate
- Deliver in the original, tightly sealed packages that have not been opened before (Catalogue number on vial the same as in white list).

2.1.4 Certified reference material (CRM)

- A copy of the validation certificates for the standard material

2.2 Columns

- Committed to the type required in the file assessment
- It must be tightly closed on both ends
- All column data must be clear and identical with the outer package in terms of type, dimensions and the serial number. The flow direction of the column must be clearly shown in the column data

2.3 Reagents

- The glass container must be tightly closed and indicate the name of the material, the batch number, and the expiration date
- It must be valid and not expired
- Good storage conditions must be adhered
- The quantity must be sufficient for analysis.

2.4 Analysis requirements for microbiology

2.4.1Antibiotic Microbial Assay

- An additional package of the reference standard material must be delivered, complying with all storage conditions, validity of data and certificate

2.4.2 Bacteria

- Commitment to proper storage conditions and validity of data and certificates
- Commitment to the requirements of the file assessment with a complete analysis certificate that matches with the sample
- Lyophilized pellet-Slant on nutrient agar not specific agar.

2.4.3 Supplement

- Delivery of the certificate
- Commitment to proper storage conditions and the accuracy of data and certificates

2.4.4 Agar

- In case the original package is not delivered, the preparation method of the original package must be attached
- Commitment to the proper storage conditions and the validity of data and certificates.

2.4.5 Enzymes

- Original, tightly sealed package.
- Commitment to proper storage conditions and the validity of data and *certificates*

3 Samples delivery

- *Ensure that the exhibit samples are intact and sealed*
- Commitment to *the required sample size (1 Annex)*
- Commitment to the proper storage conditions
- *exhibit* samples should be identical in terms of data and batch number.
- Number of seized samples should be equal to that in the withdrawal form

Samples submission requirements for the Administration of Post Approval Control

1-Documents required to be submitted to the administration of Post Approval Control

1.1 Fulfillment e mail

- A copy of the fulfillment e mail sent by the administration in the case of a new assessment pathway (local) and in the case of early assessment (imported)
- The inspection e mail in case of corresponding
- Inspection.Nodcar@gmail.com

1.2 Original copy of samples withdrawal form (Ornik)

To Assure the following:

- Sample's name
- Sample's production and expiry date
- Owner's name
- Factory name
- Pharmaceutical form
- Withdrawal reason
- Withdrawal type
- Variation samples, if any, which must be recorded in the withdrawal report
- Number of delivered

samples are identical to the seized samples and that is recorded in the withdrawal form

- In case of incorrect or modified data the inspector will sign and stamp it
- If the date of issuing withdrawal form is different from the date of issuing withdrawal report, A technical report should be submitted including the reason of reissuance.
- Storage conditions
- The name of raw material supplier which identical to that recorded in the withdrawal form and COA.

1.3 Withdrawal record

- A copy of withdrawal record
- Record any variations in the manufacturing conditions in the record
- Sample's name, batch no., country of origin and raw material suppliers should be identical to that submitted with the sample's file for assessment

1.4 Column Commitment

- The Commitment form is printed on a document bearing the company logo and stamped with the living seal.

1.5 Attachment receipt

- To view the attachment to be submitted to the Post Approval Administration, please click on the link below:
- **Attachments receipt**

1.6 payment receipt

- Original cash receipt showing the name of the product sample and not subject to deletion or modification/ automated payment slip
- Original payment of full analysis fees including Hazardous or excipients if any
- A copy of the impurity analysis fees receipt
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1.7 All analysis requirements according to the provided method in the case of Normal and Fast track samples.

1.8 The company shall deliver 2 copies of each document and place it in a folder

2. Analysis requirements

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- Matched with what has been fulfilled
- Stored under proper storage conditions.
- Attaching the certificate that containing potency, especially in the case of an EDQM standard substance

2.1.2 Working standard

- Delivering sufficient amount for analysis
- Supplier certificates
- Original copy of traceability certificates with original
- Signatures and stamp

2.1.3 White List Standard

- Ensure that the material is included in the white list
- Attach the sample certificate
- Deliver in the original, tightly sealed packages that have not been opened before (Catalogue number on vial the same as in white list).

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- Delivery of the certificate
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2.4.4 Agar

- In case the original package is not delivered, the preparation method of the original package must be attached
- Adherence to the proper storage conditions and the validity of data and certificates.

2.4.5 Enzymes

- Original, tightly sealed package.
- Commitment to proper storage conditions and the validity of data and certificates

3 Samples delivery

- *Ensure that the seized samples are intact and sealed*
- Commitment to *the required sample size (1 Annex)*
- Commitment to the proper storage conditions
- Seized samples should be identical in terms of data and batch number.
- Number of seized samples should be equal to that in the withdrawal form
- In case of raw material the samples are delivered in brown glass containers, with all data completed in the attachment receipt form.

Annex 1

Sample size of the administration of Evaluation and Approval

Approved sample size	
Dosage form	**Total**
1-Uncoated tablet	If tablet wt ≤ 100 mg Total: 470 tabs If tablet wt > 100 mg≤ 250 mg Total: 400 tabs If tablet wt > 250 mg≤ 650 mg Total: 245 tabs If tablet wt > 650mg Total: 180 tabs
2-Uncoated scored tablet	If tablet wt ≤ 100 mg Total: 500 tabs If tablet wt > 100 mg≤ 250 mg Total: 430 tabs If tablet wt > 250 mg≤ 650 mg Total: 275 tabs If tablet wt > 650 mg Total: 210 tabs
3-Film coated tablet	If tablet wt ≤ 100 mg Total: 375 tabs If tablet wt > 100 mg≤ 250 mg Total: 325 tabs If tablet wt > 250 mg≤ 650 mg Total: 205 tabs If tablet wt > 650 mg Total: 160 tabs
4-Sugar coated tablet	If tablet wt ≤ 100 mg Total: 370 tabs If tablet wt > 100 mg ≤ 250 mg Total: 320 tabs If tablet wt > 250 mg ≤ 650 mg Total: 200 tabs If tablet wt > 650 mg Total: 155 tabs

Approved sample size	
Dosage form	**Total**
5-Film coated scored tablet	If tablet wt ≤ 100 mg Total: 405 tabs If tablet wt > 100 mg ≤ 250 mg Total: 355 tabs If tablet wt > 250 mg ≤ 650 mg Total: 235 tabs If tablet wt > 650 mg Total: 190 tabs
6-Hard and soft gelatin cap	If capsule content wt ≤ 100 mg Total: 390 capsules If capsule content wt > 100 mg ≤ 250 mg Total: 340 capsules If capsule content wt > 250 mg ≤ 650 mg Total: 220 capsules If capsule content wt > 650 mg Total: 175 capsules
7-Lozenges	If lozenge wt ≤ 100 mg Total: 470 tabs If lozenge wt > 100 mg ≤ 250 mg Total: 400 tabs If lozenge wt > 250 mg ≤ 650 mg Total: 245 tabs If lozenge wt > 650 mg Total: 180 tabs
8-Capsules for inhalers	If capsule content wt ≤ 100 mg Total: 345 capsules If capsule content wt > 100 mg ≤ 250 mg Total: 295 capsules
9-Fast dissolving films	If Film wt ≤ 100 mg Total: 350 films If Film wt > 100 mg&≤ 250 mg Total: 220 films If Film > 250 mg &≤ 650 mg Total: 100 films

Approved sample size	
Dosage form	**Total**
10- Dry powder inhaler (diskus) (min 30 doses per pack)	If ≤ 30 doses Total: 42 containers If > 30 doses Total:37 containers
11- Dry powder inhaler (min 30 doses per pack)	If ≤ 30 doses Total: 40 containers If > 30 doses Total: 35 containers
12- Aerosols (Pressurized metered dose preparation for inhalation or nasal)	70 containers
13- Topical pressurized aerosols continuous dose preparation	60 containers
14- Topical pressurized aerosols metered dose preparation	70 containers
15- Sprays (Non-pressurized metered dose preparation for nasal)	65 containers
16-Powder granules in sachets giving solution (unit dose uni-component)	If wt ≤ 3 gm Total: 115 sachets If wt > 3 gm ≤ 5 gm Total: 82 sachets If wt > 5 gm Total: 80 sachets
17-Powder granules in sachets giving solution (unit dose multi-component)	If wt ≤ 3 gm Total: 125 sachets If wt > 3 gm ≤ 5 gm Total: 92 sachets If wt > 5 gm Total: 90 sachets
18-Powder granules in sachets giving suspension (unit dose uni-component)	If wt ≤ 3 gm Total: 125 sachets If wt > 3 gm ≤ 5 gm Total: 92 sachets If wt > 5 gm Total: 90 sachets

Approved sample size	
Dosage form	**Total**
19-Powder granules in sachets giving suspension (unit dose multi-component)	If wt ≤ 3 gm Total: 135 sachets If wt > 3 gm ≤ 5 gm Total: 105 sachets If wt > 5 gm Total: 100 sachets
20- Powder granules giving suspension (multidose, uni- component or multi-component)	40 containers
21- Powder granules (multidose)	40 containers
22- Supp and pessaries	130 suppositories
23- Transdermal patches	70 patches
24- Ophthalmic ointment	55 containers
25- Creams/gels/ointments	45 containers
26-Eye drops (single dose)	140 units
27-Eye drops (multiple dose)	80 containers
28-Solution (single dose) (inhalation -oral)	If volume ≤ 1 mL Total: 115 units If volume >1 mL and ≤ 2 mL Total: 110 units If volume >2 mL Total: 100 units
29-Solution and suspension multiple dose (otic -nasal -oral-topical)	If volume >1 mL and ≤ 2 mL Total: 64 units If volume >2 mL and ≤ 30 mL Total: 57 units If volume > 30 mL Total: 50 units

Approved sample size	
Dosage form	**Total**
30-Parenteral powders	If wt < 5 gm Total: 125 units If wt ≥ 5 gm Total: 95 units
31-Parenteral solution up to 20 mL	90 units
32-Parenteral solution more than 20 mL	50 units
33-Prefilled syringe containing solution and suspension	59 syringes
34-Large volume infusion > 100mL	15 units
35-Implant prefilled syringe	59 syringes
36-Solution and suspension enema	50 units

- The Central Administration of Drug Control has the right to request analysis requirements that are not available in the laboratories during the Assessment/analysis of the product, if needed.
- The Central Administration of Drug Control has the right to request additional samples if needed.