

CAPA

Ministry of Health and Population

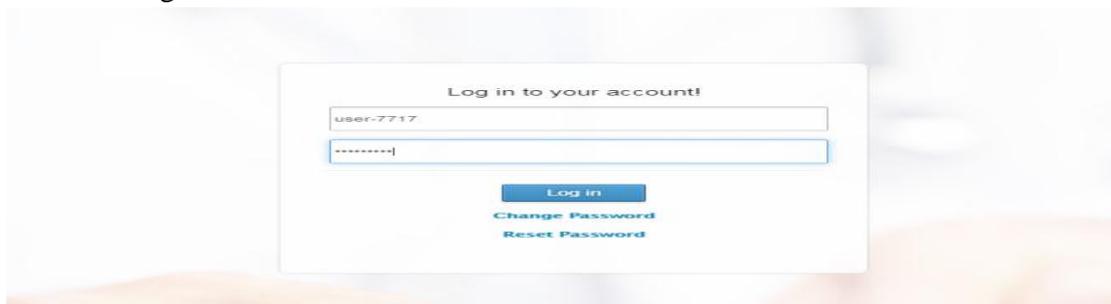
The Manual for the submission of a box inquiry for a new human drug Via the automated box program

2017

The Manual for the Submission of a box inquiry for a new human pharmaceutical drug Via the automated box Program

First Step:

- 1- The Company has to log into the Box Inquiry program via the official capa website which is www.mohip.gov.eg.
- 2- The company can log into its Account by entering its username & password in the log in screen



Second Step:

The Company has to fulfill all the following fields to submit a new box request inquiry as the following:

Fields with stars are Mandatory

Type	Company	Country
License Holder	NOVARTIS CONSUMER	HOLLAND
Primary Packager	NOVARTIS CONSUMER	HOLLAND

New Request Fields

- Bio/Human:** The Company has to choose if its new product is Human Pharmaceutical or biological.
- Receipt No.:** The Company has to enter its receipt no. (**Note:** each inquiry should have a separate receipt number as the program will not accept the entry of repeated Receipt Numbers)

- iii. **Type of license:** the company has to choose the type of license of this product acc. to the type of license the company is allowed to submit (for eg. Local, toll, f-toll, imported, bulk, under-license,.....)
- iv. **Product Type:** the company has to choose if its **new Human Drug product** is (Innovator or Imported Generic or Line Extension)
- v. **Reference:** the company should determine if its product is referenced or non-Referenced.
- vi. **Type of Reference:** The company has to choose its submitted product Reference from the drop down list in case of referenced products only (Note: the new submitted product & the reference product should be matched in the following: the same Active ingredient, Strength, Dosage Form, Pack)
- vii. **Min.Decree No.:** 425 or 820 in case of human Pharmaceuticals / 297 or 820 in case of Biological.
- viii. **Manufacturer:** to determine the manufacturer name only in Case of local/Toll/Under license Products.

Note: in case of imported / bulk/under license/ toll-Under license products the following Fields need to be Fullfilled:

- ix. **CPP:** The Company has to determine the country of origin from which the CPP has been issued.
- x. **Type:** the Company should enter each type of the companies have been mentioned in the CPP of the product (for eg. License Holder, Manufacturer , Primary Packager, secondary packager, M.A.H,)
- xi. **Search Company:** the company has to type at least 3 letters of the company name then press enter then choose the company name from the drop down list and it will consequently turn into orange.
- xii. **Search Country:** the company has to type at least 3 letters of the country of the chosen company then press enter then choose the Country from the drop down list and it will consequently turn into orange.
- xiii. **Add Company:** After choosing both the company name & country (in orange) press add Company.
- xiv. **Add Other:** in case if the company name was not found in the drop down list, choose country first to then type the company name in a text then press Add other.

Attachments

- i. **CPP:** A copy of valid Stamped CPP has to be uploaded (at least the first 6 pages of the CPP)
- ii. **Receipt Attachment:** A scanned copy of the receipt should be uploaded (The generic, strength, D.F of the Submitted product should be Written on the receipt)(Note: the receipts that have a correction or abrasion will be rejected)
- iii. **Reference Attachment:** A valid Authorized copy of the reference has to be uploaded.
- iv. **Registration Letter or Pricing:** For Line Extension products applicant should upload either: Registration license, pricing license or pricing submission receipt of the original product (Document must be valid)
- v. **Other Attachments:** In case of the presence of other attachments.
- vi. **Add Receipt:** the company has to enter the no. of other receipts (if required) then upload it then press add receipts.

The screenshot shows the 'Attachments' section of a web application. It includes a list of attachment types with 'Choose File' buttons: CPP, Receipt attachment *, Reference attachment, Registration Letter or Pricing, and Other Attachment. Below this is a 'Receipt No' input field with a 'Choose File' button, and 'Add Receipt' and 'Delete Receipt' buttons. A table below shows a receipt with ID '54895475' and type 'Other Receipts'.

Generic Details

The screenshot shows the 'Generic Details' form. It includes fields for: Generic Type (Single), Pharmacotherapeutic Group (Analgesic), Trade Name in the Reference (perfalgan), Indication (Treatment of pain), Link for the Reference Product (https://www.accessdata.fda.gov/scripts/cder/dat/), Search Generic Name (paracetamol), Symbol (=), Strength Value (10), Search Strength Unit (mg/ml), Search Dosage Form (solution), Search Route (inject), and Package Information (Pack of 100 ml vial). There are also dropdown menus for Generic Name (PARACETAMOL), Unit (mg/ml), Dosage form (Solution, Solution for injection, Solution in prefilled pe, Solution in Prefilled Sy, Solution+Tablet), and Route (INJECTION, injection/inhalation, injection/ophthalmic).

i. Generic Type:

- **Single:** in case of human drug products that have only one Active Ingredients.
- **Combination:** In case of human drug products that have more than one Active Ingredient.
- **New Generic:** In case of human drug products have only one or more than one Active Ingredient and not **found in the drop down List of the Generic name search**, the company has to type the name of the new Generic in text.
- **Combo Pack:** In case of submission of new human drug Products in the form of a combo Pack.

- ii. **Pharmacotherapeutic Group:** The Company has to write the pharmacotherapeutic Group of the new submitted drug acc. to the reference in a text.
- iii. **Indication:** The Company has to write the Indication of the new submitted drug acc. to the reference in a text.
- iv. **Trade name in the reference:** The Company has to type the name of the reference product of the new submitted drug in text.**(Mandatory)**
- v. **Link for the reference product:** the Company has to copy the URL of the reference product in this field.
- xv. **Search Generic name:** the company has to type at least 3 letters of the submitted Generic name then press enter then choose the Generic name from the drop down list and it will consequently turn into orange.
- vi. **Symbol:** the company has to choose "=" in case of new Pharmaceutical human drugs.
- vii. **Strength Value:** the Company has to type the Strength Value in text (For eg. 10, 0.137, 600,)
- xvi. **Search Strength Unit:** the company has to type the Strength value then press enter then choose it from the drop down list and it will consequently turn into orange. (For eg: mg/1ml, gm,Litre)
- xvii. **Search Dosage Form:** the company has to Type at least 3 letters of the submitted Dosage Form then press enter then choose it from the drop down list and it will consequently turn into orange.
- xviii. **Search Route:** the company has to Type at least 3 letters of the Route of administration then press enter then choose it from the drop down list and it will consequently turn into orange.
- viii. **Package Information:** the Company has to write the Package Information of the new submitted drug acc. To the reference in a text (For e.g. Pack of 10 Ampoules each of 2ml)
- xix. **Dose Type:** as in case of injection the company has to determine if it is single or multiple.

Note:

In case of combination: the company should enter the first Active ingredient with all its details then press enter then choose it and it will consequently turn into orange then press save, the request will appear in the request history below the company should choose it then add the second ingredient with its symbol, strength value, strength unit then press enter then choose it and it will consequently turn into orange then press save then Choose the request from the request history and repeat this process for each active ingredient in the combination.

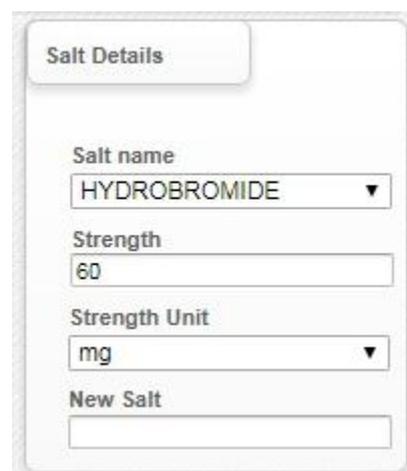
Salt Details

Salt name: the company has to choose the salt name of each active ingredient from the drop down list (Acc. to the submitted reference).

Strength: the Company has to type the Strength of the salt in text.

Strength Unit: the company has to choose the salt Strength unit from the drop down list.

New Salt: the company has to type the name of the new Salt in a text, in case of new salts that are not found in the drop down List of salt name.



The screenshot shows a form titled "Salt Details" with the following fields: "Salt name" (a dropdown menu with "HYDROBROMIDE" selected), "Strength" (a text input field containing "60"), "Strength Unit" (a dropdown menu with "mg" selected), and "New Salt" (an empty text input field).

Submission of the request



A horizontal bar containing four blue buttons: "Confirm", "Save", "Delete Generic", and "New Request".

- i. Save:* the company has to press save so that the request inquiry will appear in the requests history (Below) With an ID but with no status , in this stage the company can modify its request & can add generics in case of combination, before pressing confirm.
- ii. Confirm:* By pressing confirm the request with all its details & attachments will be delivered to capa to be investigated, the status of the request in the requests history (Below) will be changed to Delivered.
- iii. Delete Generic:* if the company needs to delete a generic before it confirms its request inquiry.
- iv. New Request:* if the company needs to add a new request.

Requests History

Requests History				Generic Details			Salt Details			Request Attachments
Id	Status	Date		Generic Name	Strength Value	Unit	Salt	Strength	Unit	Type
2	Info Required	2017-09-16		PARACETAMOL	= 500.0000	mg	No data to display			
3	Under revision	2017-09-14								
10	Delivered	2017-09-17								
15	Delivered	2017-09-18								

- i. **Requests History:** this list will include all the requests that have been confirmed by the company with their ids, status & date of sending.
- ii. **status :** will be changed to be one of the following
 - *Delivered:* means that this request has been delivered to boxes team to be investigated.
 - *Under Revision:* means that this request has been Preliminary investigated by boxes team (within Max. 3days) & it has been accepted to be received & will be revised for the box status.
 - *Rejected:* means that this request has been Preliminary investigated by boxes team (within Max. 3days) & it has some comments that need to be corrected. This means that this request has not been received by boxes team & the company needs to resubmit it with all its correct details by a new date.
 - *Accepted:* means that the request has been revised for the box status & accepted, the company will receive hard copy of box approval.
 - *Refused:* means that the request has been revised for the box status & Refused.
 - *Info Required:* means that the request has been revised for the box status & need some requirements that will be sent by capa to the company, in order to continue the revision process of box status.

CAPA Comment

CAPA Comment: this box will have the comments that are required by boxes Department to be clarified from the company's side.

CAPA Comment

1- determine the pack in details
 2- send a list of your reg. & under reg products