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CONFERENCE

Using the CEP Procedure to elevate quality and drive trust

23-24 September 2025 | Budapest, Hungary

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Relying on CEPs – Egyptian Drug Authority's perspective

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Egyptian Drug Authority

Agenda

1. EDA Overview
2. Reliance practice
3. API Listing
4. API Tool

01

EDA Overview

An Independent Public Service Authority Directly Affiliated to the Egyptian Prime Minister

Before August 2019

CAPA

Central Administration of Pharmaceutical Affairs

NODCAR

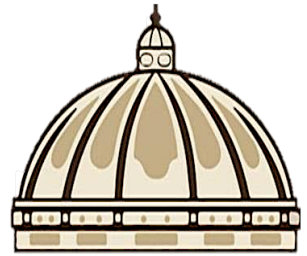
National Organization for Drug Control and Research

NORCB

National Organization For Research and Control of Biologicals

EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية



Law no. **151** of **2019**

ratified by President Sisi on 25 August 2019

Decree No. **777** of **2020**

issued by Prime Minister on 29 March 2020

Executive Regulations

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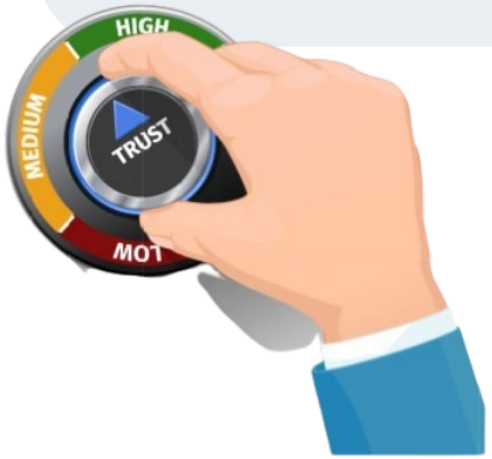
International Accreditation

EDA is the first African NRA to achieve WHO ML3 for both Medicines and Vaccines - Producing



March 2022,
December 2024

02

Reliance Practice

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For Finished Products

Reliance Pathways Eligibility Criteria & requirements

Verification Route

1-Product approved by **at least two SRAs**
Or Product approved in **one SRA & WHO** prequalification

2-Verification of full sameness of Product for local market is similar with that approved by SRA
(Sameness + Including CMC)

Abridged Route

1-Product approved by at least one SRA
Or WHO prequalification

2-Verification of sameness of Product for local market is similar with that approved by SRA

CTD

CPP

GMP

Sameness letter

Unredacted Ass. report

For Active Pharmaceutical Ingredients

Relying on CEPs

Normal Evaluation

3.2.S.1 General Information
3.2.S.2 Manufacture
3.2.S.3 Characterization
3.2.S.4 Control of the API
3.2.S.5 Reference standards or materials
3.2.S.6 Container-closure system
3.2.S.7 Stability

CEPs Reliance Pathway

3.2.S.1.3 General properties
3.2.S.3.1 Elucidation of structure and other characteristics
3.2.S.4.1 Specification
3.2.S.4.2 / 3.2.S.4.3 Analytical procedures and validation
3.2.S.4.4 Batch analysis
3.2.S.5 Reference standards or materials
3.2.S.6 Container closure system
Exception: where
the CEP specifies a container closure system and the applicant / FPP manufacturer declares to use the same
container closure system.
3.2.S.7 Stability
Exception: where the CEP specifies a re-test period that is the same as or of longer duration, and storage
conditions which are the same or higher temperature and humidity as proposed by the applicant.

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03

API Listing

Purpose of API Listing

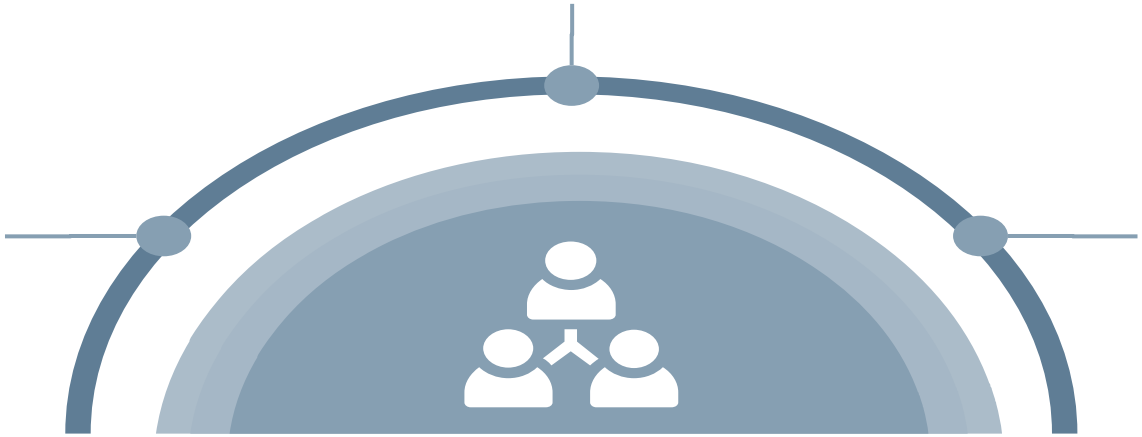
1- Ease of selection of API suppliers with confirmed high-quality standards of their drug substances.

2- Saving time of evaluation of Quality CTD file (only P-Part will be evaluated).

APIs are Listed by:

Egyptian API Manufacturer.

Imported API Manufacturer.



MAH of finished pharmaceutical product.

API Listing

Total Listed APIs

288

- 2A1
- 42A2
- 244A3

Number of APIs

151

Total Users

362

Total APIs with more than 1 supplier 48
Total APIs with the same supplier with different monographs 9

API Listing

Total Listed APIs

288

CEP

35

	API Name	DMF / CEP Holder Name	DMF version number/CEP number (Applicant & Restricted part):	Date of issuing appr	Approval Expiry d	API Referen	Listing Applicant
265	Nebivolol Hydrochloride	Cadila Pharmaceuticals Limited - India	RO-CEP 2022-095 - Rev 00	3-Jun-2025	3-Jun-2030	Ph.Eur.	Averroes Pharma for Pharmaceutical Industries **(A.3)**
266	Telmisartan	Zhejiang Huahai Pharmaceutical Co., Ltd. China.	R1-CEP 2009 -077-Rev 02	11-Jun-2025	11-Jun-2030	Ph.Eur.	Parkville Pharmaceuticals Egypt **(A.3)**
267	Mirabegron	Honour lab limited - India	**Applicant Part:** AP-00,August,2020 **Restricted Part:** RP-00,July-2021	11-Jun-2025	11-Jun-2030	Ph.Eur.	Future Pharmaceutical Industries **(A.3)**
268	Anastrozole	Hetero labs Limited, India	**Applicant part:** AP 12-July 2023 **Restricted part:** RP [EM], 19- November-2021	15-Jun-2025	15-Jun-2030	Ph.Eur.	Pharmed health care **(A.3)**
269	Imatinib Mesylate	Hetero labs Limited, India	CEP 2018-222-Rev 04	15-Jun-2025	15-Jun-2030	Ph.Eur.	Pharmed health care **(A.3)**
270	Fingolimod Hydrochloride	Honour Lab Limited, India	RO-CEP 2019-171 - Rev 01	15-Jun-2025	15-Jun-2030	Ph.Eur.	Elixir Pharma **(A.3)**

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API Tool

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API SEARCHING TOOL

This innovative tool offers detailed information on active pharmaceutical ingredients, including:

- Inclusion in the EDA White List.
- Available Scientific References (Pharmacopeias)
- Key Influential Properties on Substance Quality (CQA- Critical quality attribute)

Since 24/9/2024

روابط الخدمات الإلكترونية

EDA HERBA MONOGRAI

EDA SIMILARS

API SEARCHING TOOL

EDDB Egyptian Drug Database قاعدة بيانات الدواء المصري

BOX Inquiries الاستعلام عن صندوق المثائل

Naming Inquiries الاستعلام عن أسماء البطاقات

EDA API SEARCHING TOOL

API Name : None (1)

Listing Status
No data

EDA Specific Guidance
No data

Reference
No data

Name(s) of pharmacopia(s)
No data

Critical Quality Attributes CQA
No data

Listing Data

DMF / CEP Holder Name	DMF version number/CEP number	API Reference	Listing Applicant	Valid till
No data				

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EDA API SEARCHING TOOL

API Name : Amlodipine (As besilate) (1)

Listing Status
Listed on EDA White List

EDA Specific Guidance
NA

Reference
Pharmacopeial

Name(s) of pharmacopia(s)
United States Pharmacopeia
European Pharmacopeia
British Pharmacopeia
Japanese Pharmacopeia

Critical Quality Attributes CQA
This data is under construction

Listing Data

DMF / CEP Holder Name	DMF version number/CEP number	API Reference	Listing Applicant	Valid till
Hetero Labs Limited, India	"Applicant part: AP [EM], 27-April, 2023(USP) Restricted part: RP [EM], 22-Auguest, 2023"	USP	Hetero labs Limited (A.2)	Sep 4, 2029
Cadila Pharmaceuticals Limited - India	Applicant Part: CPL/AD/AP/348 Ver.28, March 2022 Restricted Part: CPL/AD/CP/452 Ver.06 , August 2020	Ph.Eur./BP	Utopia Pharmaceuticals (A.3)	Apr 26, 2028

EDA API SEARCHING TOOL

API Name : Ammonium Chloride (1)

Listing Status

Not Listed

EDA Specific Guidance

https://www.edaegypt.gov.eg/media/wfndxscc/note-to-applicant-guidance-on-atypical-api.pdf

Reference

Pharmacopeial

Name(s) of pharmacopia(s)

United States Pharmacopeia

European Pharmacopeia

British Pharmacopeia

Critical Quality Attributes CQA

This data is under construction

Listing Data

DMF / CEP Holder Name	DMF version number/CEP number	API Reference	Listing Applicant	Valid till

Notice to applicant

Central Administration for Pharmaceutical Products
General Administration of Human Pharmaceuticals Registration
Administration of Technical Affairs for Human Pharmaceuticals

Notice to applicant

Guidance on Atypical Active Pharmaceutical Ingredients for Medicinal Products

Year 2023

Code: EDREX: NP. CAPP.066
Version No: 1
Issue Date: 24-08-2023
Effective date (if needed): 24-08-2023

Annex I: List of Atypical Active Pharmaceutical Ingredient (AAPI)

1	Sodium Chloride
2	Magnesium Chloride
3	Calcium Chloride
4	Carboxymethyl Cellulose (sodium salt)
5	Cellulose (as Methylcellulose) and Derivatives
6	Citric Acid
7	Sodium Sulfate
8	Magnesium Carbonate
9	Magnesium Oxide
10	Sodium Acetate
11	Sodium Bicarbonate
12	Sodium Hydroxide
13	Zinc Oxide
14	Potassium Chloride
15	Ammonium Chloride
16	Glucose / Dextrose
17	Glycerol / Glycerin
18	Sorbitol
19	Mannitol
20	Polyethylene Glycol
21	Propylene Glycol
22	Silicone

Note: List will be updated periodically.

Notice to applicant

Central Administration for Pharmaceutical Products
General Administration of Human Pharmaceuticals Registration
Administration of Technical Affairs for Human Pharmaceuticals

Notice to applicant

Guidance on Atypical Active Pharmaceutical Ingredients for Medicinal Products

Year 2025

Code: EDREX: NP. CAPP.066
Version No: 2
Issue Date: 03-08-2025
Effective date (if needed): 03-08-2025

Annex I: List of Atypical Active Pharmaceutical Ingredient (AAPI)

1	Sodium Chloride
2	Magnesium Chloride
3	Calcium Chloride
4	Carboxymethyl Cellulose (sodium salt)
5	Cellulose (as Methylcellulose) and Derivatives
6	Citric Acid
7	Sodium Sulfate
8	Magnesium Carbonate
9	Magnesium Oxide
10	Sodium Acetate
11	Sodium Bicarbonate
12	Sodium Hydroxide
13	Zinc Oxide
14	Potassium Chloride
15	Ammonium Chloride
16	Glucose / Dextrose
17	Glycerol / Glycerin
18	Sorbitol
19	Mannitol
20	Polyethylene Glycol
21	Propylene Glycol
22	Silicone
23	Sodium Citrate
24	Potassium Bicarbonate

Note: List will be updated periodically.

DMF sections	Required (R)/ Optional (O)	Notes
3.2.S.1 General Information		
3.2.S.1.1 Nomenclature	R	
3.2.S.1.2 Structure	R	
3.2.S.1.3 General Properties	R	
3.2.S.2 Manufacture		
3.2.S.2.1 Manufacturer(s)	R	
3.2.S.2.2 Description of Manufacturing Process and Process Controls	R	Brief description with manufacturing process flowchart including materials used
3.2.S.2.3 Control of Materials	O	
3.2.S.2.4 Controls of Critical Steps and Intermediates	O	
3.2.S.2.5 Process Validation and/or Evaluation	O	
3.2.S.2.6 Manufacturing Process Development	O	
3.2.S.3 Characterization		
3.2.S.3.1 Elucidation of Structure and other Characteristics	O	
3.2.S.3.2 Impurities	R	Brief description of possible impurities
3.2.S.4 Control of Drug Substance		
3.2.S.4.1 Specification	R	From both API manufacturer and finished product manufacturer
3.2.S.4.2 Analytical Procedures	O	
3.2.S.4.3 Validation of Analytical Procedures	O	
3.2.S.4.4 Batch Analyses	R	Certificates of analysis (COA)
3.2.S.4.5 Justification of Specification	R	
3.2.S.5 Reference Standards or Materials		
3.2.S.5 Reference Standards or Materials	O	
3.2.S.6 Container Closure System		
3.2.S.6 Container Closure System	R	Brief description only
3.2.S.7 Stability		
3.2.S.7 Stability	O	

Notes:

1. Free TSE/BSE declaration is required.
2. Additional data may be required if deemed necessary.

API Name : Etoricoxib (1)

Listing Status

Listed on EDA White List

EDA Specific Guidance

NA

Reference

Non- Pharmacopeial

Name(s) of pharmacopia(s)

NA

Critical Quality Attributes CQA

https://edaegypt-my.sharepoint.com/:b:/g/personal/hdr_qualitymodule_edaegypt_gov_eg/EQjduQszFLxKjIm04QxifEMBvNr80uCLkv_6BcbchfT-Uw?e=DNFckN

Listing Data

DMF / CEP Holder Name	DMF version number/CEP number	API Reference	Listing Applicant	Valid till
Assurgen Pharma Private Limited, India	Applicant part: APPL/ETC/AP/00/062019 Restricted part: APPL/ETC/RP/00/062019	In-House	To Lead for Pharmaceuticals (A.3)	Oct 1, 2029
Cadila Healthcare Limited - India	"Applicant Part: AP/ETB/L/Ver.000 , 29-June-2020 Restricted Part: RP/ETB/L/Ver.000 „ 05-February-2021	In-House	Apex pharma (A.3)	Mar 25, 2029
Virdev Intermediate Pvt. Ltd. India	Applicant part: CTD/AP/VIPL/ETO/01/07 Restricted part: CTD/RP/VIPL/ETO/01/06	In-House	Liptis For Pharmaceuticals and Medical Products (A.3)	Dec 31, 2028
Kekule Pharma Limited-India	Applicant Part: KPL/ACE-IH/AP-01/03-2023 Restricted Part: KPL/ACE-IH/RP-02/03-2023	In-House	Incandesce (A.3)	Sep 10, 2028
Hetero Labs Limited Unit I, India	Applicant Part: AP [EM], 01-July-2021 Restricted Part: RP [EM] 12 January 2022	In-House	Al Andalous for pharmaceutical industries II hormone (A.3)	Jul 9, 2028
PRUDENCE PHARMA CHEM, INDIA	Applicant part: AP/ETX/C/03 Restricted part: RP/ETX/02	In-House	Julphar Plus (A.3)	Jun 25, 2028
Kekule Pharma Limited-India	Applicant Part: KPL/ACE-IH/AP-00 /12-2022 Restricted Part: KPL/ACE-IH/RP-01,March 2021	In-House	El Delta for Pharmaceutical Industries – Delta Pharma (A.3)	May 23, 2028

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Central Administration of Pharmaceutical Products

General Administration of Human Pharmaceuticals Registration

Administration of Technical Affairs for Human Pharmaceuticals

Critical Quality Attributes (CQAs) of Etoricoxib

Parameter	Relevant Data
Solubility	Etoricoxib is a substance with pH dependent solubility. It has a high solubility in the gastric media at low pH, whereas its solubility decreases as pH increases. [1] Etoricoxib is freely soluble in methanol, tetrahydrofuran, dimethyl sulfoxide, methyl ethyl ketone, dimethyl formamide, and chloroform. Etoricoxib is soluble in isopropyl acetate, ethanol and toluene, sparingly soluble in 2-propanol, and practically insoluble in water. [2]
Polymorphism	Several Etoricoxib polymorphic forms (Forms I-V; Forms IX-XVI), two hydrate forms and one amorphous form have been reported. [3] It has been reported that forms IV and V are more thermodynamically stable than forms I-III, but we have surprisingly found out that form I prepared in essentially pure form resists to any conversion and is stable under technological process conditions such as milling, compression or blending with excipients. Another advantage of form I is better solubility in comparison to polymorphic forms IV and V which can afford to improved pharmacological properties such as bioavailability. [3] Evidently, etoricoxib containing even small amounts of hemihydrate form would convert during time to undesired physical form, whereas pure polymorphic form I has no tendency to conversion. Consequently, pure polymorphic form I is preferably used for incorporation into pharmaceutical compositions. [3]
Degradation	Forced degradation studies have shown sufficient stability but Etoricoxib has been found to undergo massive degradation in response to oxidative conditions. Considering literature information about photolytic degradation processes under certain circumstances, sufficient photo stability of drug substance has been demonstrated. [4] According to the forced degradation study, Etoricoxib was found to be susceptible to degradation by base hydrolysis and oxidation. [5]

Notes:

The selection of the critical quality attributes of the drug substance is the responsibility of the applicant.

References:

1. Patent WO2016015776A1, Pharmaceutical composition of etoricoxib.
2. Patent WO2021124044A1, Pharmaceutical composition of cyclooxygenase – 2 inhibitors.
3. Patent EP2714676B1, A Process for The Preparation of Polymorphic Form I of Etoricoxib.
4. Public Assessment Report of Etoricoxib Zydus 30/60/90/120 mg film-coated tablets Etoricoxib.
5. Public Assessment Report of Etoricoxib - 1 A Pharma / Etoricox-Hexal 30 / 60 / 90 / 120 mg Filmtabletten Etoricoxib.

THANK YOU

For Further information

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Website https://edaegypt.gov.eg/

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