Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

Circular No. 56 / 2021

08 -08-1442 H

22 -03-2021

TO ALL DRUG STORES AND LOCAL MANUFACTURERS

After Compliments,

Sub: Registration/re- registration of Health Products

We would like to inform you that in order to improve the process of registration / re-registration of Health Products, we have decided to implement the below mentioned updates with immediate effects:

1. All re-registration submissions must not include variations. The company must submit a declaration letter of no changes along with the application.
2. Incase if there are changes while its due for re- registration, the company must submit a separate variation application either in parallel or after its renewal.
3. To use the attached **Form HP-version 2** for any new registration/re- registration application for Health Products. The form is also available in our website.

Thank you for your kind understanding and cooperation..

Yours faithfully,

Dr. Mohammed Hamdan Al Rubaie
Director General

Encl: a/a

cc: DDC
Director (cQCL)
SH (Registration Section of Herbal & Health Products)
SH (Analysis Section of Herbal & Health Products)

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
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سلطنة عمان
وزارة الصحة
SULTANATE OF OMAN
MINISTRY OF HEALTH

PADC

APPLICATION FORM FOR HEALTH PRODUCT (HP)

- Application form to be filled by typing ONLY (original & one photocopy).
- All the documents submitted with this application should be in either English or Arabic.
- Arrangement of the documents in the folder should follow the same sequence followed in this form.
  - Registration file as a hard copy
  - Quality Control Laboratories (QCL) file as a soft copy ONLY (CD)
- Each strength, dosage form, flavor or packaging material should be submitted as a separate dossier.
- **Implementation of Child Resistance Cap (CRC) on all liquid preparation*.**
- **Implementation of identification codes on tablets*.**
- **Implementation of safety seals on all outer packs.**
- Fees for each product is 300RO and for each additional pack size is 150RO.

Type of Application:

☐ New

☐ Re-Regiseration** Reg. No. with MOH: _____

PART I: (*To be filled by Local Agent*)

1. Name & Address of the Local Agent:

Address	Administration Office
P.O. Box	.....
P. C.	.....
Tel. No.	.....
Fax No.	.....
E-Mail	.....

2. Full Description of the Product:

2.1	Trade name		
2.2	Dosage form*		
2.3	Route of administration		
2.4	Pack size (by weight, volume or number of doses)		
2.5	Type of packaging material*		
2.6	Shelf life		
2.7	Storage conditions in figures		
2.8	Legal category	☐ OTC	☐ GSL
		☐ POM	☐ Others, specify .....

3. Detailed Composition of the Product:

Name of active ingredient	Quantity	Quality standard (USP,...)

4. Manufacturer Details:

4.1	Company Name	
4.2	Address	
4.3	Reg. No. with MOH (if available)	

5. Marketing Authorization Holder (MAH) Details:

5.1	Company Name	
5.2	Address	
5.3	Reg. No. with MOH (if available)	

6. Batch Releaser Details:

6.1	Company Name	
6.2	Address	
6.3	Reg. No. with MOH (if available)	

Name & Signature of the Authorized Pharmacist in the Pharmacy

_____

_____

Stamp of the Pharmacy

PART II: (*To be filled by the Manufacturing Company*)

Registraion File:-

s.	Administrative Documents	Yes	No
1.	A copy of valid drug store licence issued by MOH, Sultanate of Oman		
2.	A letter from the company confirming that the applicant is the local agent in the Sultanate.		
3.	A copy of commercial registration certificate issued by Ministry of Commerce & Industry indicating that the applicant is the agent of the company in the Sultanate.		

s.	Manufacturer Documents	Yes	No
1.	legalized and valid Certificate of Good Manufacturing Practice (cGMP) for the manufacturer issued by the regulatory authorities & attessted by Oman embassy in country of origin (COO).		
2.	List of affiliated branches & related manufacturers with address		
3.	List of countries in which the company is registered		
4.	List of the products manufactured by the Company		
5.	If MAH is different from the manufacturer - Legalized and valid Certificate e.g. cGMP, Good Distribution Practice (GDP) certificate or ISO of the MAH issued by the regulatory authorities & attested by Oman embassy in COO. - A certificate showing the relation between the two companies (MAH & manufacturer)		

s.	Product Documents	Yes	No
1.	Legalized and valid Certificate of Pharmaceutical Product (CPP) (WHO Certification Scheme or similar) or Free Sale Certificate (FSC) issued by the regulatory authorities & attested by Oman embassy in COO.		
2.	List of countries where the product is registered & marketed supported by photocopies of registration certificates (if available).		
3.	Scientific report containing: - Composition formula (Active & Inactive ingredients) - Pharmacological effects / mode of action - Therapeutic category - Indications - Dosage regimen & route of administration. - Precautions, warnings & contraindications - Adverse Effects - Drug interactions - Incompatibilities - Use time period (shelf life after opening) - when applicable - Over dosage (briefly state symptoms, non-drug treatment. - Supportive therapy & specific anti-dote - if available.		

	- Advantage claimed over similar other product if any. - Legal category in COO - List of References & Publications.		
4.	Certificate issued from the company and legalized by the concerned authorities in (COO) showing that the products do not contain hormones, heavy metals, antibiotics, steroidal products, pork derivatives or any other natural or chemical materials which affect the behavior and bio-functions of human (and if the product contains ingredients of animal origin, type of animal to be stated and the part from which material is taken and alcohol percentage should be stated with reasons for its use, **alcohol content should be in following ranges:** - 0.5% for children below 6 years - 5% children between 6 and 12 years - 10% above 12 years		
5.	Certificate issued from the company and legalized by the concerned authorities in (COO) showing that the preservatives, colorants and diluents present in the formula are permitted by the international health authorities.		
6.	**For products containing herbal ingredient(s):** - Summary of the profile of the plant used including botanical name, genus, species, plant part used, weather cultivated or wild, harvesting practices and treatment to obtain raw material. - Data to demonstrate the safety of each herbal ingredient in human beings e.g. through bibliographic or scientific studies. - Description of physiological functions of the herbal ingredients / supplements to the intended user.		
7.	Pack insert (if available) legalized by the regulatory authorities in (COO) and 2 specimens of the pack insert are required in both languages Arabic & English. It should contain the following: - Trade name - Pharmaceutical dosage form - Composition - Pharmacological action - Indications - Dosage & Administrations - Side effects - Contraindications - Drug interactions - Precautions & Warnings (during pregnancy, lactation and the other special cases) - Over dosage & antidote - Storage conditions in degree centigrade - Other available pharmaceutical dosage forms, pack sizes and concentration of the active ingredients. - Manufacturer/MAH details - Number and date of revision of the pack insert		

8.	Two specimens of inner/ outer labels for every pack size are required in both languages Arabic & English. It should contain the following: - Trade name - Active ingredients and concentration - Route of administration - Batch number, manufacturing and expiry dates - Dosage - Direction of use - Indications - Warnings and precautions - Contraindications - Special usage guidelines - Pack size - Storage conditions in degree centigrade - Manufacturer company name, address & logo		
9.	Description of packaging material specifications		
10.	CD containing outer pack, inner pack, pack insert		
11.	Two samples + Batch Analysis Certificate (BAC)		
12.	Product classification letter issued by MOH (if available)		
13.	****For re-registration application, submit the following:** - Photocopy of product registration certificate issued by MOH - Declaration letter from the company stating that there are no changes on the product other than what have been approved previously by DGPA&DC. - Approval letters for post variations after its initial registration		

Quality Control Laboratories (QCL) File:

Sr. no.	Requirements	Submission (√ / x)		Remarks
		To be filled by Manufacturer	To be filled by Evaluator	
1	**Updated composition formula with the quantities in (g/ml) or (mg/tab) for all the active & inactive ingredients a long with the function of each.**			□ Complete. □ Incomplete, Form 'S' Attachment: _____
2	**Updated finished product specification with physical, chemical and microbiological test parameters including limit of acceptance for the assay test for all the active ingredients.**			□ Complete. □ Incomplete, Form 'S' Attachment: _____
3	**Certificate of Analysis for finished products**			□ Complete. □ Incomplete, Form 'S' Attachment: _____
4	Detailed **validated method of analysis** along with **supportive chromatograms** for: - Determination of all **active ingredients and preservatives** in the finished product. - **Microbial limit and heavy metals tests** in the finished product. See Annexure (1).			□ Complete. □ Incomplete, Form 'S' Attachment: _____
5	**Stability study** to support the proposed shelf life, as per the claimed storage condition, if required.			□ Complete. □ Incomplete, Form 'S' Attachment: _____
6	**Reference standards that cover three analysis, as per the relevant circular for active ingredients, impurities & preservatives (if applicable) along with their batch analysis certificate.** ***			□ Complete. □ Incomplete, Form 'S' Attachment: _____
7	**10 packs** of finished product **sample** for analysis along with their certificate of analysis. ***			□ Complete. □ Incomplete, Form 'S' Attachment: _____
8	**Chemical reagents & chromatographic columns** (if required). ***			□ Complete. □ Incomplete, Form 'S' Attachment: _____

Annexure (1):

1. Detailed method of analysis for all the active ingredients in the FINISHED PRODUCT including the followings:

- Preparation of Reference standards (weight to be taken and the diluent).
- Preparation of the samples of FINISHED PRODUCT (weight to be taken and the diluent).
- Chromatographic condition (column used, wavelength, injection volume, content of mobile phase).
- Chromatograms for the assay test of each active ingredient.
- Detailed calculation of the assay test.

***** Please note that points 6, 7, 8 will be requested after 1st evaluation report (form S).**

Declaration

I hereby certify that all the information filled in this form, all submitted documents are true and accurate, and changes will not be made until they are approved by MOH, Oman.

Name & Signature of the Authorized Pharmacist in the Company

_____

_____

Official Stamp of the Company

FOR OFFICIAL USE ONLY

☐ Received ☐ Not received

Checked by (Reg.)	: _____	**Checked by (QCL)**	: _____
Signature	: _____	**Signature**	: _____
Date	: _____	**Date**	: _____

COMMENTS:

_____

_____

_____

Record No.	: _____	**Date**	: _____

(ZYNEX - 40 CAPSULES 40MG) (0004) (HG-001173-00-00-00)

Registration Type : POST REGISTRATION - (Variation - Followup)

VI. M2 and M3 Assessments:

PROPOSED CHANGES :-
Change in pellets composition of the finished product: (20% Excess solution instead of 100 % to be considered in the sub coating and enteric coating of the pellets).

FINISHED PRODUCT AND EXCIPIENT(S) :-
In response to our requirements in attachment (1), the manufacturer submitted long term stability study data carried out at 30C/65%RH on three batches for 24 months, the same is considered acceptable to support the product change sought.

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