| REQUIRED INFORMATION/DOCUMENTS FOR LOCALLY NON-REGISTERED PRODUCTS | | | |
|---|---|---|---|
| **TENDER REFERENCE** | | **SUPPLIER REFERENCE** | |
| **ITEM DESCRIPTION:** | | | |
| **QUESTION** | **REQUEST** | | **Company Comments** |
| 1-Product manufacturer site(s)/ country of origin. | Please provide valid WHO standard GMP/GDP/WDA or equivalent certificates of all manufacturing & packaging sites. | | |
| 2-Marketing Authorization Holder / country of origin. | Please provide valid GDP/WDA or equivalent from the governmental competent health authority. | | |
| 3-Supplier Name / Exporting country. | Please provide valid GDP/WDA or equivalent from the governmental competent health authority. | | |
| 4-Is this product licensed to:<br>a-be placed on the market for use in the exporting country or<br>b-for export only? | a (Please provide supportive documents and product license number) /<br>b (Clarify reasons) | | |
| 5-Is this product actually on the market as a finished product in the exporting country? | Yes/No | | |
| 6-Is the offered product and its mentioned information complete and consonant with its license in the certifying country of export? | Yes/No | | |
| 7-Please confirm the product classification in the certifying country of export? | Pharmaceuticals, Herbal/Dietary/Food Supplement, active pharmaceutical ingredients (APIs)…. etc. (specify) | | |
| 8-Please provide relevant available product certificates and proof of prior registration under GCC-DR, EMA, FDA, Swissmedic, TGA, Health Canada, … | *CPP (Certificate of Pharmaceutical Product). | | |
| | *FSC (Free Sale/Trade Certificate). | | |
| | *(Alcohol content declaration letter) on the official manufacturer's letterhead stating that the product is free from alcohol. | | |
| | *(Pork content declaration letter) in the official manufacturer's letterhead stating that the product is free from any materials of pork/porcine source. | | |
| | *(Certificate of suitability for TSE) Transmissible Spongiform Encephalopathy). | | |

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|---|---|---|---|
| | *Non-Genetically Modified Organism (Non-GMO) declaration letter. | | |
| | *CoA (Certificate of Analysis). | | |
| | *Others (specify).. | | |
| 9-Please provide product labels, artwork & leaflet (for the actual product not for a sample) as marketed in the certifying country of export. | *Product Label (immediate & secondary packaging). | | |
| | *Artwork in full color (outer, inner pack). | | |
| | *Patient Information Leaflet (PIL) and | | |
| | *Summary of Product Characteristics (SPC). | | |
| 10-Have you supplied this product to HMC before? | Yes (provide PO#)/<br>No | | |
| 11-Please provide authorization letter for exclusive/distributorship of this product in the state of Qatar. | (If available). | | |

HMC/PHARMA-MAY/2022

Authorized/ Responsible Company Representative: Company Official Stamp

Name:

Date - Signature