

**MINOR VARIATION NOTIFICATION FORM FOR FULL EVALUATION PRODUCTS**

Please read the following instructions before filling in the form.

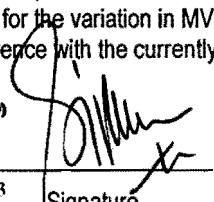
- 1) This notification form is for Product Registration Holder (PRH) to notify National Pharmaceutical Control Bureau (NPCB) on the implementation of MiV-Notification (MiV-N) as per Malaysian Variation Guideline (MVG). The timeline for NPCB to acknowledge the variation notification is within 20 working days following receipt of a notification.
- 2) Please refer to the MVG for the conditions and supporting documents required.
- 3) Submission of relevant revised draft of package insert and labeling is subject to current regulatory requirements as per the latest Drug Registration Guidance Document (DRGD) and Circulars from NPCB. In the event that the revised draft of package insert and labeling does not meet the current regulatory requirements, please submit under Minor Variation Prior Approval (MiV-PA) or Major Variation (MaV).
- 4) PRH **must** submit this notification form together with the online submission through the Quest 2 system as the approval will only be notified via online submission. For submission online, please scan this form and attach together with the revised draft of package insert and labeling as a single file.
- 5) A MiV-N application may be rejected in specific circumstances with the consequence that the PRH must cease to apply the already implemented variation.
- 6) The completed form must be submitted to :  
**Seksyen Variasi, Pusat Pasca Pendaftaran Produk, Biro Pengawalan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia, Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor. (Fax No: 03-79567151)**

|                                                           |  |                                                                                                                                                                  |  |
|-----------------------------------------------------------|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Product Name:<br><b>LOFRAL 10MG TABLET</b>                |  | Name and address of product registration holder:<br><b>MEPHARM (MALAYSIA) SDN.BHD.<br/>15, JALAN USJ 1/19, TMN SUBANG PERMAI<br/>47600 SUBANG JAYA, SELANGOR</b> |  |
| Reference Number: 2006053027325                           |  | Tel. No.: 03-5636 8088                                                                                                                                           |  |
| Registration Number: MAL07031138AC                        |  | Fax No.: 03-5636 8133                                                                                                                                            |  |
| Date of online submission in Quest System: <b>4/12/13</b> |  | Email address: simonwong@mepharm.com                                                                                                                             |  |

| Variation No. | Minor Variation (Notification)                                                                                                     | Please tick (✓)<br>Multiple selection is allowed |
|---------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| MiV-N1        | Change of details of product registration holder                                                                                   |                                                  |
| MiV-N2        | Change of importer and/or store address                                                                                            |                                                  |
| MiV-N3        | Change of product owner                                                                                                            | ✓                                                |
| MiV-N4        | Change in ownership of manufacturer                                                                                                |                                                  |
| MiV-N5        | Change of the name or address (for example: postal code, street name) of the manufacturer of drug product                          |                                                  |
| MiV-N6        | Change of the name or address (for example: postal code, street name) of the company or manufacturer responsible for batch release |                                                  |
| MiV-N7        | Change of the name and/or address (for example: postal code, street name) of a manufacturer of the drug substance                  |                                                  |
| MiV-N8        | Withdrawal/deletion of the alternative manufacturer(s) for drug substance                                                          |                                                  |
| MiV-N9        | Renewal of European Pharmacopoeial Certificate of Suitability (CEP)                                                                |                                                  |
| MiV-N10       | Change of specifications of the drug product and/or drug substance and/or excipient, following the updates in the compendium       |                                                  |
| MiV-N11       | Deletion of pack size for a product                                                                                                |                                                  |

I hereby notify NPCB on the minor variation by notification for the product(s) above and declare that

- ✓ There is no other change except for the proposed variation;
- ✓ The change(s) will not adversely affect the quality, efficacy and safety of the product;
- ✓ All conditions for the variation concerned are fulfilled;
- ✓ The required supporting documents as specified for the variation in MVG have been submitted; and
- ✓ The proposed change has been checked in reference with the currently approved data in the system & there are no discrepancies.

|                              |                                                                                                                                                         |                                                                                                  |                        |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|------------------------|
| <b>WONG YOON YOU</b><br>Name | <b>Mepharm (Malaysia) Sdn Bhd (349607-D)</b><br>15 Jalan USJ 1/19<br>47600 Subang Jaya Selangor Darul Ehsan<br>Tel: (03) 5636 8088 Fax: (603) 5636 8133 | <br>Signature | <b>4/12/13</b><br>Date |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|------------------------|

June 2013



Note: Lot No./Batch No., Mfd. & Exp. Date will be printed on the label during manufacturing.



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|----------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------|--|
| <b>Acino Pharma AG</b>                                                     |  | <b>Prog.-Nr.: 30220-4112</b>                                                                              |  | <b>GUT ZUM DRUCK</b>                                                     |  |
| Format: 40x27x115 mm<br>ZAZ:                                               |  | ZDB: 1019195-0004-ZDB-000-01                                                                              |  | <div><div>Gut zum Druck</div><div><input type="checkbox"/></div></div>   |  |
| Art.-Nr.: <b>30220-4112</b><br>Produkt: Lofral 10 Tab OP30 EAA (FS) 4      |  | SA-Nr.: 4035743 / Jacqueline FRIEDL<br>SA SMK: bauer@backstage / P2 / 11-JAN-13<br>KD-Auftrag: 4500090873 |  | <div><div>Nochmals Proben</div><div><input type="checkbox"/></div></div> |  |
| <b>Farben:</b> Black Cyan Magenta Yellow<br>PANTONE 417 C<br>PANTONE 877 C |  | <b>Rondo</b><br>Gewerbstrasse 11<br>CH-4123 Allschwil<br>T +41 61 486 87 87<br>F +41 61 486 87 50         |  | <div><div>Datum:</div><div>Unterschrift:</div></div>                     |  |
| <b>Technische Farben:</b> Stanzkontur                                      |  |                                                                                                           |  | <div></div>                                                              |  |