



Agensi Regulatori Farmasi Negara
National Pharmaceutical Regulatory Agency
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia



Tel: +603-78835400
Faks: +603-79562924 / 79581312
<http://npa.moh.gov.my/>

GMP Certificate No.

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part I

The National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia confirms the following:

The Manufacturer :

Site Address :

Malaysia.

Has been inspected in accordance to Malaysian Control of Drugs and Cosmetics Regulations 1984 and Malaysian Drug Registration Guidance Document (DRGD).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on _____ it is considered that it complies with the principles and guidelines of the current Pharmaceutical Inspection Co-Operation Scheme (PIC/S) GMP Guides.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts I and II.

The authenticity of this certificate may be verified with the issuing authority.

Senior Principal Assistant Director
Centre for Compliance and Licensing
Date : 21 SEP 2016

Page 1 of 3





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GMP Certificate No.:

Part II

√ Human Medicinal Products	
3. MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES	
3.1	Manufacture of active substance by chemical synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation/purification steps: Crystallization
3.5	General Finishing Step
	3.5.1 Physical processing steps (Drying, blending & micronization)
	3.5.2 Primary packaging
	3.5.3 Secondary packaging
3.6	Quality Control Testing
	3.6.1 Physical/chemical testing

Active Substances:

- | | |
|-----|-----|
| 1. | 15. |
| 2. | 16. |
| 3. | 17. |
| 4. | 18. |
| 5. | |
| 6. | 19. |
| 7. | 20. |
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| 9. | 22. |
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| 14. | 27. |

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Page 2 of 3



MS
Certified to ISO 9001:2008
Cert. No. AR 2193



Member of
Pharmaceutical Inspection
Cooperation Scheme



Non Member Adherence to
Mutual Acceptance
of Data for GLP



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GMP Certificate No.

28.	42.
29.	43.
30.	44.
31.	45.
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36.	49.
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38.	51.
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40.	53.
41.	

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Page 3 of 3

