

DOCUMENTS TO BE SUBMITTED FOR ISSUE OF CERTIFICATES

REQUIREMENTS FOR ISSUE OF G.M.P/G.L.P. CERTIFICATE

1. Covering letter indicating the purpose of GMP/GLP Certificate
2. Copies of Manufacturing Licence in Form 25 / 28/32/25B/28D/25A/28A/28DA.
3. Copy of the GMP/GLP Certificate issued earlier if any.

REQUIREMENTS FOR ISSUE OF WHO-GMP CERTIFICATE

1. Copies of Manufacturing Licence in Form 25 / 28.
2. List of applied products.
3. Product summary sheet with the details of date of first approval, stability and process & analytical validation.

REQUIREMENTS FOR ISSUE OF CERTIFICATE OF PHARMACEUTICAL PRODUCTS [COPP]

1. Covering letter indicating the purpose of COPP.
2. Copy of valid W H O-G M P Certificate
3. Copies of Master formula Records- wherever required.
4. Copies of the Product approvals for applied drugs.
5. Copies of Manufacturing Licence in Form 25 / 28.

REQUIREMENTS FOR ISSUE OF FREE SALE CERTIFICATE

1. Covering letter indicating the purpose of Free Sale Certificate
2. List of the Products requiring Free Sale Certification
3. Copies of Manufacturing Licence in Form 25 / 28.
4. Copies of the Product approvals for applied drugs.

5. Proof of availability of same product in Indian Market, with similar labels

REQUIREMENTS FOR ISSUE OF A MARKET STANDING CERTIFICATE

1. Covering letter indicating the purpose of Market Standing Certificate
2. List of the Products required Market Standing Certificate
3. Copies of Manufacturing Licence in Form 25 / 28.
4. Copies of the Product approvals for applied drugs.
5. Certificate issued by the Chartered Accountant certifying the Production and Sales activities for the period required along with certain invoices for the applied products for the required period.
6. Format of the Certificate in the Tender Form.

REQUIREMENTS FOR ISSUE OF PERFORMANCE CERTIFICATE

1. Covering letter indicating the purpose of Performance Certificate
2. Format of the Certificate in the Tender Form if any.
3. List of the Products required Performance Certificate
4. Copies of Manufacturing Licence in Form 25 / 28.
5. Copy of the GMP /WHO-GMP Certificate issued earlier.
6. Copies of the Product approvals for applied drugs.
7. Certificate issued by the Chartered Accountant certifying the Production and Sales activities for the period required along with certain invoices for the applied products for the required period.

FOR NON CONVITION CERTIFICATE

1. Covering letter indicating the purpose of Non-conviction Certificate
2. Copies of Manufacturing Licence in Form 25 / 28.
3. Self declaration on non-judicial stamp paper stating that the licensee has not been convicted earlier for the violations of provisions of D& C Act, 1940 and Rules 1945.

REQUIREMENTS FOR ISSUE OF NEUTRAL CODE CERTIFICATE

1. Covering letter indicating the purpose of Neutral Code Certificate
2. Copies of Manufacturing Licence in Form 25 / 28.
3. Copy of the list of products meant for export.

REQUIREMENTS FOR ISSUE OF PRODUCTION CAPACITY CERTIFICATE

1. Covering letter with brief introducing the firm with factory and Office address and purpose of production capacity certificate.
2. Format of the Certificate in the Tender Form if any.
3. List of the dosage forms whose production capacities are to be certified.
4. Copies of Manufacturing Licence in Form 25 / 28.
5. Manufacturing capacity of each dosage form along with the capacity of equipment.