



| Requeriments                                                   | Category |                     |                  |                              |           |
|----------------------------------------------------------------|----------|---------------------|------------------|------------------------------|-----------|
|                                                                | Foods    | Dietary Supplements | Natural Products | Cosmetics / Hygiene Products | Drugs     |
| <b>Approval Times (months)</b>                                 | <b>6</b> | <b>12</b>           | <b>12</b>        | <b>6</b>                     | <b>12</b> |
| <b>Legal Documentation*</b>                                    |          |                     |                  |                              |           |
| Power of Attorney                                              | NA       | x                   | x                | x                            | x         |
| Certificate of Free Sale**                                     | x        | x                   | x                | x                            | x         |
| Certificate of Good Manufacturing Practices***                 | NA       | x                   | x                | x                            | x         |
| Manufacturer - Holder Quality Agreement                        | NA       | x                   | x                | x                            | x         |
| <b>Technical Documentation</b>                                 |          |                     |                  |                              |           |
| Qualitative-Quantitative Formula****                           | x        | x                   | x                | x                            | x         |
| Finished Product Specifications                                | NA       | x                   | x                | x                            | x         |
| Certificate of Analysis                                        | NA       | x                   | x                | x                            | x         |
| Analytical Methodologies                                       | NA       | x                   | x                | NA                           | x         |
| Validation of Analytical Methodologies                         | NA       | NA                  | NA               | NA                           | x         |
| Stability Study                                                | NA       | NA                  | NA               | NA                           | x         |
| Artwork Designs in PDF                                         | x        | x                   | x                | x                            | x         |
| Scientific support for health claims, gluten free, Kosher, etc | x        | x                   | x                | NA                           | x         |
| Technical Data*****                                            | x        | x                   | x                | x                            | x         |
| Pharmacological Monograph                                      | NA       | NA                  | x                | NA                           | x         |
| Quantity of Product Samples                                    | 6        | NA                  | 6                | NA                           | 6         |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>Notes or additional comments</b>                                                                                                                                                                                                                                                    |       |
| All legal documentation must be apostilled.                                                                                                                                                                                                                                            | *     |
| Must have the full name of the company name of the Holder and manufacturer                                                                                                                                                                                                             | **    |
| It must mention the category and pharmaceutical form of the products it manufactures.                                                                                                                                                                                                  | ***   |
| Must be on letterhead, signed and stamped by the holder.                                                                                                                                                                                                                               | ****  |
| Should be on letterhead, signed and stamped by the holder and should contain the following information (Name of the product, a brief description of the use, name of the manufacturer, quali-quantitative formula, nutritional table, net content, shelf life and storage conditions). | ***** |
| Not applicable                                                                                                                                                                                                                                                                         | NA    |
| For products with small and liquid presentation, the number of samples can be increased to 12                                                                                                                                                                                          |       |
| Please note that in Guatemala all sanitary registrations are presented in Spanish, so we must translate all the documentation we receive.                                                                                                                                              |       |

