

# ALLEGATO 2 della Determinazione: Format del certificato GMP

<b>3 MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES</b>	
Active Substance(s):	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	3.1.1 <i>Manufacture of active substance intermediates</i> 3.1.2 <i>Manufacture of crude active substance</i> 3.1.3 <i>Salt formation / Purification steps : &lt;free text&gt; (e.g. crystallisation)</i> 3.1.4 <i>Other &lt;free text&gt;</i>
<b>3.2</b>	<b>Extraction of Active Substance from Natural Sources</b>
	3.2.1 <i>Extraction of substance from plant source</i> 3.2.2 <i>Extraction of substance from animal source</i> 3.2.3 <i>Extraction of substance from human source</i> 3.2.4 <i>Extraction of substance from mineral source</i> 3.2.5 <i>Modification of extracted substance &lt;specify source 1,2,3,4&gt;</i> 3.2.6 <i>Purification of extracted substance &lt;specify source 1,2,3,4 &gt;</i> 3.2.7 <i>Other &lt;free text&gt;</i>
<b>3.3</b>	<b>Manufacture of Active Substance using Biological Processes</b>
	3.3.1 <i>Fermentation</i> 3.3.2 <i>Cell Culture &lt;specify cell type&gt; (e.g. mammalian / bacterial )</i> 3.3.3 <i>Isolation / Purification</i> 3.3.4 <i>Modification</i> 3.3.5 <i>Other &lt;free text&gt;</i>
<b>3.4</b>	<b>Manufacture of sterile active substance (sections 3.1, 3.2, 3.3 to be completed as applicable)</b>
	3.4.1 <i>Aseptically prepared</i> 3.4.2 <i>Terminally sterilised</i>
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 <i>Physical processing steps &lt; specify &gt; (e.g. drying, milling / micronisation, sieving)</i> 3.5.2 <i>Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> 3.5.3 <i>Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</i> 3.5.4 <i>Other &lt;free text&gt; (for operations not described above)</i>
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 <i>Physical / Chemical testing</i> 3.6.2 <i>Microbiological testing (excluding sterility testing)</i> 3.6.3 <i>Microbiological testing (including sterility testing)</i> 3.6.4 <i>Biological Testing</i>

**4. OTHER ACTIVITIES- ACTIVE SUBSTANCES**

<free text>

Any restrictions or clarifying remarks related to the scope of this certificate:

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...../...../..... [date] .....

Name and signature of the authorised person of the Competent

Authority of [country]

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[name, title, national authority, phone & fax numbers]