

1. Manufacturing process / Route of Synthesis

We, <u>(manufacturer name)</u>, <u>(address)</u>, inform that we manufacture the material <u>(material name)</u>, registered in the CAS under the number <u>(CAS number)</u>, through the synthesis route presented below:

TEMPLATE		
Starting material ————— Intermediate # 1		
Chemical name or CAS number of all the solvents used Chemical name or CAS number of all reagents (acids, filter aid, chromatographic resins,etc.) used in this step	bases, salts, cataly	
Intermediate # 1		
Chemical name or CAS number of all the solvents used Chemical name or CAS number of all reagents (acids, I filter aid, chromatographic resins, etc.) used in this step:	bases, salts, catalys	
Intermediate # n Product Chemical name or CAS number of all the solvents used Chemical name or CAS number of all reagents (acids, I filter oid observations at a) used in this step.	bases, salts, catalys	
filter aid, chromatographic resins, etc.) used in this step: Observation: The template above should be replaced b		thesis of the mater
The material supplied to Matrix Fine Chemicals should always be obtained through the same route of synthesis as presented above	☐ I agree	☐ I disagree
No reprocessed or reworked material should be supplied to Matrix Fine Chemicals	☐ I agree	☐ I disagree
We are committed to inform Matrix Fine Chemicals of any intention of changing the manufacturing process of this material before the implementation of the change	☐ I agree	☐ I disagree
The material will not be manufactured, purified or processed in any other address different from the one mentioned above	☐ I agree	☐ I disagree



specification presented below:

We declare that we are willing to be inspected concerning the manufacture of this material, if requested by Matrix Fine Chemicals	☐ I agree	☐ I disagree
2. Physico-chemical and microbiological sp	pecification	
We, <u>(manufacturer name)</u> , <u>(address)</u> , inform that <u>name</u>), registered in the CAS under the number		

(Insert the table of specifications)

We are committed to always supply the material according to the specification presented above	☐ I agree	\Box I disagree
We are committed to disclose the analysis method description to Matrix Fine Chemicals, in order to achieve a harmonization with the quality control laboratory from Matrix Fine Chemicals or their appointed quality control facility	□ I agree	☐ I disagree
We are committed to analyze all the batches supplied to Matrix Fine Chemicals, forward the CoA before each shipment and to maintain the raw data for eventual audits	☐ I agree	☐ I disagree
We are committed to inform Matrix Fine Chemicals of any intention of changing in the specification and / or analytical method of this material before the implementation of the change	☐ I agree	□ I disagree



3. Undesired contaminants

The material supplied to Matrix Fine Chemicals is manufactured in multipurpose equipments (reactors, centrifuges, filters, ovens, fluidized bed flows)?	☐ Yes	□ No	
In case the answer to the question above is yes, vegetare that the equipment are adequately cleaned after each production of different materials		☐ I disagree	
We are committed to perform the packaging of the final product in the commercial packaging under conditions where no crossed contamination may occur	□ I agree	☐ I disagree	
The temporary or definitive packaging of the product should always be performed in new and duly identified packaging	☐ I agree	☐ I disagree	
We declare that highly sensitizing materials (such penicillins and cephalosporins) are not manufactured in the same equipment used for manufacturing the material supplied to Matrix Fine Chemicals	☐ I agree	□ I disagree	
In case of highly active substances or toxic materials (such as hormones, cytostatic or other potentially toxic materials) being produced in the same area and using the same equipment used in the manufacturing of the material, adequate procedures for the inactivation and/or cleaning should be established	□ I agree	□ I disagree	
I confirm that all the information presented in this quality commitment are true and given in good faith.			
(Signature of the responsible person and			
date)			
(Complete name of the responsible person) (Job position of the responsible person)			
(Job position of the respons	oivie heisoii)		



TO BE FILED BY MATRIX FINE CHEMICALS:		
The commitment to quality has been reviewed and deemed approved.		
Name:		
Signature:	Date:	