

A. INFORMATION:

1. A copy of manufacturing process, step-wise as submitted along with the application.
2. Step-wise time required and total time to complete the process and obtaining the finished product.
3. Location of manufacturing unit along with telephone/FAX number, where the process is proposed to be demonstrated and sample is to be drawn, it should be the same as given in the application.
4. A copy of claimed chemical composition, along with a copy of method of analysis of the product and impurities, ATR,IR,UV,NMR, Mass spectra along with all chromatograms.

B. UNDERTAKING:

“We, M/s _____, hereby undertake that:-

1. We have in readiness all facilities and raw-materials needed for the demonstration of process of manufacturing as given in application of registration.
2. We have in readiness reference standard of the product and standard impurities as per given chemical composition, for making available to in-process sample drawing officers on the date of his visit readily.
3. We are ready to demonstrate the process and drawl of sample during the period from _____ to _____ (six weeks time).

(SIGNATURE & SEAL OF APPLICANT)”

ON RECEIPT OF THE ABOVE INFORMATION, THE OFFICIALS SHALL BE DEPUTED FOR DRAWL OF IN-PROCESS SAMPLE.