

MEMORANDUM OF UNDERSTANDING

BETWEEN

ASOJ SOFT CAPS PVT.LTD. (Dist. Vadodara, Gujarat)

AND

H.R.Patel Institute of Pharmaceutical Education and Research,
(Shirpur, Dist.- Dhule, Maharashtra. India)

ASOJ SOFT CAPS PVT.LTD. (ASOJ), is a company working in the area of Pharmaceutical product development using novel or innovative formulation approaches, facilitating the development, technology transfer and commercialization of such novel products.

And

H.R.Patel Institute of Pharmaceutical Education and Research, (Shirpur, Dist-Dhule, Maharashtra) is engaged in the academics.

As **ASOJ** and **H.R.Patel Institute of Pharmaceutical Education and Research, Shirpur** have common interest of promoting research & development as well as conversion of laboratory research into improved healthcare products, both has agreed to enter into an AGREEMENT to promote Pharmaceutical & Biotechnological development of conventional and novel drug delivery system (NDDS) based innovative products. Both the organizations have agreed to work together on following terms and conditions:

There are no pre-determined limits to the activities, which might be involved in such collaboration, but they will be directed toward the following specific objectives.

- 1) Both the organizations strive hard to raise the research and teaching standards by developing collaborative R & D projects in the area of Pharmaceutical and Biotechnological science in order to fully utilize and nurture the expertise and facilities available at both the organization including the man power.
- 2) To facilitate greater involvement of research scholars as well as academic members of staff at both the organization in research areas such as the development of successful




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Pharmaceutical and Biotechnological products and collaborations with national and international organizations of high standards.


- 3) To exploit the synergy arising from the joint initiatives to improve the effectiveness and efficiency of teaching and research in both organization as well as to undertake research projects from different agencies both in India and abroad.
- 4) To attract funding and other supports from industry, government organizations and abroad funding agencies through higher critical mass of research and teaching activities created by the collaborations.
- 5) Priority will be given to secure businesses from various national and international industries in joint efforts.
- 6) Senior and junior academic staff in full time, permanent employment will undertake exchange visits to fulfill the aims and objectives of the MOU.
- 7) Priority will be given to filing joint patents and publications of high international standards.
- 8) Any patenting out of the joint collaborative research efforts will be equally shared between both the Organizations.
- 9) Periodic board meetings between the two Organizations to discuss the plans of the testing and research etc. will be conducted at the end of every three months.
- 10) This MOU shall be in operation for a maximum period of 3 years from the date of signing. However, this depends upon the decision to be taken at the end of the every year after a thorough discussion with all the board members and scientists involved depending upon its progress and financial gain to recommend for further continuation of MOU for the next subsequent year until the end of the MOU period of 3 years.
- 11) **ASOJ and H.R.Patel Institute of Pharmaceutical Education and Research, Shirpur** will work together synergistically and interdependently with a common goal to develop the predetermined, Pharmaceutical and Biotechnological product(s) within a pre-determined slot of time. However, presently, ASOJ will only be involved in the research, development and analysis of the product development cycle.



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- 12) The aforesaid "Pharmaceutical and Biotechnological *product(s)*" mean conventional Pharmaceutical and Biotechnological dosage forms such as tablets, capsules, syrups, suspensions, emulsions, ointments, creams, gels etc., as well as novel or innovative drug delivery systems such as liposomes, microparticles, microemulsions, nanoparticles, nanoemulsions, implants, transdermal drug delivery systems etc. These Pharmaceutical and Biotechnological products would be developed so as to display certain predetermined characteristics such as immediate, controlled (sustained, timed, delayed, and pulsatile) or targeted drug release.
- 13) Both generic and new drug products would be considered for development and commercialization. The generic drug product development would be carried out with the intention to obtain a product that is bioequivalent to the existing FDA approved drug product while the advanced, novel/ innovative drug delivery systems would be developed for new drugs or to overcome the drawbacks of existing drug/ drug product.
- 14) In order to develop these and other similar research based products, sophisticated instrumentation and high tech infrastructure is needed. Thus, **ASOJ and H.R.Patel Institute of Pharmaceutical Education and Research, Shirpur** would collaborate with the intention to strengthen each other's R & D capabilities and to deliver effective, safe and quality Pharmaceutical and Biotechnological products for their own growth and for the benefit of the society.
- 15) For smooth running of this collaborative effort, a common organized committee (COC) would be formed that would include two representatives each from ASOJ and **H.R.Patel Institute of Pharmaceutical Education and Research, Shirpur**. The committee would be responsible for making key decisions regarding administration and management of the development process. The tasks of this committee would involve defining the roles of both the organizations, selection of products for development, worldwide regulatory and IPR status of the drug or drug product, technical, scientific and commercial feasibility of the product, defining the milestones and timelines for development process of candidate products, costing of the project, status review of under development product(s) etc.
- 16) ASOJ would be responsible for analytical method development, formulation development, toxicological studies, partial documentation support (preparation of specifications, certificate




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of analysis, product development report), partial support for regulatory approval (preparation of Common Technical Document or dossier for DCGI approval) and scientific support for marketing literature.


- 17) **H.R.Patel Institute of Pharmaceutical Education and Research, Shirpur** will provide any technical support that may be required by ASOJ during the development of the product. This may include the use of formulation, research, analytical and college facilities. Both the organizations would be free to take the services of any third party if needed and in situations when a particular facility is not available at their sites.
- 18) Each new product that is taken up for development shall be considered as one project. Various such projects could be taken up by mutual understanding at one point of time.
- 19) ASOJ shall hold the exclusive marketing rights of the developed products. ASOJ shall also be the applicant for any patent that emerges out of the research and shall bear all the filing expenses. However name of the scientists from **H.R.Patel Institute of Pharmaceutical Education and Research, Shirpur** involved in the project shall be included in the patent.
- 20) **Exclusivity and linkages with other Industries and Institutes:** This agreement is being entered into on a non-exclusive basis and both the parties are free to enter into similar or other agreements with other industries or academic institutes. Additionally, if nature of a project/ development work so demands, then ASOJ and **H.R.Patel Institute of Pharmaceutical Education and Research, Shirpur** can also jointly enter into an agreement with a third party. The third party may be an institute or industry.
- 21) **Duration of Agreement:** That this agreement is being entered into for a period of two years from date of signing of the agreement.
- 22) **Modification of the agreement:** In the interests of improvement or better facilitation of organizational linkages, if the parties so desire the agreement may be modified as per mutual consent and such modification may involve addition, deletion or alteration of any clause. Such modification may be duly mentioned on the body of the main agreement and details attached with the agreement as 'addendum'.
- 23) **Dispute Resolution:** That any difference or dispute arising between the parties under this agreement shall be settled amicably in the larger interest of cooperation & goodwill and the




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interest of the researchers & profession involved. Unresolved dispute, if any shall be referred to the sole arbitration of a person nominated by both the parties. The award of the arbitrator shall be final and binding. The arbitration shall be conducted as per provision of arbitration and conciliation Act, 1996. The seat of arbitration shall be Ahmedabad, Gujarat. Courts at Ahmedabad, Gujarat., shall have exclusive jurisdiction in all matters arising under this agreement.

IN WITNESS WHEREOF this agreement is signed on this day of 29/11/2019 in Shirpur Dist-Dhule, Maharashtra




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For **H.R. Patel Institute of Pharmaceutical Education & Research, Shirpur Dist. Dhule (M.S.)-425 405**
H.R. Patel Institute of Pharmaceutical Education and Research, Shirpur


Director / Principal

Seal:

Witness 1




Dr. V. K. Chaturvedi



For **ASOJ SOFT CAPS PVT. LTD.**
Technical Director

Seal:

Witness 2



29/11/19
D. A. Patil

Dated: 29/11/19

Place: Shirpur.