

Home > TopNews

you can get e-magazine links on WhatsApp. [Click here](#)

**Health & Insurance**

+ Font  
- Resize



Pharmabiz e-pape



60% COATING TIME SAVER  
MORE PRODUCTIVITY ECONOMICAL

Want to B

Pharma polymers For  
cGMP compliance production facil



Pharmabiz e-pape

Want to B



# Health ministry vets proposal for validated method of extracting CP at cost-effective price for treatment of COVID-19 patients

*Shardul Nautiyal, Mumbai*

*Monday, August 3, 2020, 08:00 Hrs [IST]*

In order to rationalize pricing of convalescent plasma (CP) for treatment of COVID-19 patients, the Union health ministry is currently vetting a proposal from state drug regulatory authorities and healthcare institutions to come out with a validated method of extracting CP other than plasmapheresis methods at a cost-effective price prescribed by the National Blood transfusion Council (NBTC).

Plasma has generally been extracted from whole blood through centrifuge method at most of the blood banks in the country at NBTC stipulated price ranging between Rs. 200 and Rs. 400. Experts have pinpointed that cost of plasmapheresis is at a higher cost of Rs.11,000 and most of the blood banks don't have plasmapheresis machines to extract CP which Indian Council of Medical Research (ICMR) has approved for clinical trials and CP therapy for COVID-19 patients.

As per ICMR guidelines, plasma collection will be done by centrifugal separation using apheresis machine or equipment at the healthcare facility. This comes close on the heels of the Maharashtra Food and Drug Administration (FDA) also having issued directives to blood banks to strictly follow NBTC prescribed pricing guidelines for CP through plasmapheresis method from the donor recovered from COVID-19. There are increasing reports across the country that CP is being sold at exorbitant prices evading guidelines.

Plasmapheresis is a method of removing blood plasma from the body by withdrawing blood, separating it into plasma and cells and transfusing the cells back into the bloodstream.

According to pharma consultant Dr Sanjay Agrawal, "CP therapy is more or less like a vaccine as it contains antibodies against the infected disease. There is no need to invest time in searching for other alternatives as CP therapy is the most effective remedy today for COVID-19."

As part of the protocol to donate plasma for COVID-19 patients, Maharashtra FDA directives stipulate that the recipient should furnish doctor's prescription and his/her identity details to keep a tab on black marketing.

The Central Drugs Standard Control organization (CDSCO) recently came out with a set of new criteria on CP therapy based on Union health ministry's guidelines to monitor patients post transfusion for any transfusion related adverse events. Prerequisites as per new criteria while considering donor for CP transfusion include ABO compatibility and cross matching of the donor plasma. This also includes neutralizing titer of donor plasma should be above the specific threshold. If the latter is not available, plasma IgG titer (against S-protein RBD) above 1:640 should be used.

Use of CP should be avoided in patients with IgA deficiency or immunoglobulin allergy and dose should be variable ranging from 4 to 13 ml/kg (usually 200 ml single dose given slowly over not less than 2 hour).

Guidelines on 'Clinical Management Protocol: COVID-19' by the Union health ministry were released on June 27, 2020. According to Union health ministry guidelines, CP may be considered in patients with moderate disease who are not improving (oxygen requirement is progressively increasing) despite use of steroids.

CDSCO had in April 2020 granted no objection for conduct of clinical trials for CP therapy as per protocol developed by ICMR. The same has been approved subject to certain amendments in the protocol and various conditions under the new Drugs and Clinical Trial Rules 2019. As per the protocols, plasma donors will be explained the procedure of plasma donation and the adverse events associated with the process. Among the consenting donors and based on the results, donors will be asked to return on a specified date for plasma donation.

Practical way of using blood effectively is to separate its various components into red blood concentrates, fresh frozen plasma, cryo-precipitates and platelet concentrates to rationally use blood and maintain its availability. Whole blood can be of use to four patients at one time. One unit of blood gives components of packed red blood cells, random donor platelets, fresh frozen plasma and cryoprecipitate.