Technical Specification of Artesunate Injection Kit under NCVBDC

Particulars	Description
A. Specific requirements	Artesunate Injection Kit consists of a vial of **Artesunate** Injection; an ampoule of 5% Sodium Bicarbonate Injection; an ampoule of Sodium Chloride Solution and Disposable Syringe along with Disposable needle. The individual items contained in the product shall also be currently registered in India having valid drug manufacturing license issued by relevant Indian license issuing authority. Artesunate Injection: Description: Artesunate Injection contains a sterile powder containing Artesunate. Each vial shall contain - Artesunate IP 60 mg The injection is reconstituted as per manufacturer instructions, immediately before use. The quality of Artesunate injection should conform to the requirements of Indian Pharmacopoeia, latest edition and must be accompanied by in-house test reports of the batch supplied. (I.P stands for Indian Pharmacopoeia)
Labeling:	The label on each vial shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time. The label shall indicate **"NVBDCP, Dte.GHS SUPPLY- NOT FOR SALE"**.
Packing: **Primary Package**	5 ml Vial (IP type 1 clear) (Containing Artesunate Powder for injection) closed with 20 mm Bromobutyl Rubber Plug and Sealed with flip off seal and plastic overcap.
Sodium Bicarbonate Injection:	
Description:	A clear, colourless solution. Each ampoule shall contain 1 ml of Sodium Bicarbonate Injection I.P. (5%W/v). The quality of Sodium Bicarbonate injection should conform to the requirements of Indian Pharmacopoeia, latest edition and must be accompanied by in-house test reports of the batch supplied. *(I.P stands for Indian Pharmacopoeia)*

Labelling:	The label on each vial shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time. The label shall indicate **"NVBDCP, Dte.GHS SUPPLY- NOT FOR SALE"**.
Packing: **Primary Package:**	IP Type 1 clear plain glass ampoules. Each ampoule shall contain 1 ml of Sodium Bicarbonate injection I.P. (5%w/v). The ampoule should be transparent to permit visual inspection of the contents.
Sodium Chloride Injection:	
Description:	A clear, colourless solution. Each ampoule shall contain 5 ml of Sodium Chloride Injection I.P. (0.9%W/v). The quality of Sodium Chloride injection should conform to the requirements of Indian Pharmacopoeia, latest edition and must be accompanied by in-house test reports of the batch supplied. *(I.P stands for Indian Pharmacopoeia)*
Labelling:	The label on each vial shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time. The label shall indicate **"NVBDCP, Dte.GHS SUPPLY- NOT FOR SALE"**.
Packing: **Primary Package:**	IP Type 1 clear plain glass/FFS ampoule. Each ampoule shall contain 5 ml of Sodium Chloride injection I.P. (0.9%w/v). The ampoule should be transparent to permit visual inspection of the contents.
Disposable Syringe and Disposable Needle:	
Description (Disposable Needles):	Sterile Hypodermic Needles for Single Use comprise of a length of hypodermic grade stainless steel tube connected to a hub that is designed to mate with a syringe or an IV set. They shall conform to the standards given in IS 10654:2002. The other end of the tube is sharpened at the tip as per IS requirements. The tube is covered with a shield made from polypropylene. The hub fabricated from poly propylene is colour coded as per the requirements of ISO 6009. The union of the hub and needle tube is carried out with epoxy adhesive. This medical device in conjunction with Syringe is intended for immediate use for administration of injectable preparations. They are supplied sterile and pyrogen– free and not to be re-sterilized or reused. The Hypodermic needles shall comply with the following standards regarding Dimensions:

Labeling: (Primary)	The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time. The label shall indicate **"NVBDCP, Dte.GHS SUPPLY- NOT FOR SALE".**
Packing: **Primary Package:**	Each syringe and needle shall be packed and sealed separately in a primary container. The material of each container should not have detrimental effects on the contents. The material and design should be such as to ensure: 1. The maintenance of sterility under dry, clean and adequately ventilated storage conditions; 2. The minimum risk of contamination of the contents during opening of the container and removal of the contents; 3. Adequate protection of the contents during normal handling, transit and storage; 4. That once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened. Paper-PVC Blister: PVC Film: Transparent, clear, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns. • Hard tempered Blister paper, VMCH coated, Thickness: 0.025mm
Secondary Package:	The primary package should be packed in boxes for easy handling, transport and distribution. The box may contain --- primary packages. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 400gsm.
Labelling on Shipper Package:	The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.
Secondary Package for Atresunate Injection + Sodium bicarbonate Injection + Sodium Chloride Injection:	
Description	One vial of Artesunate Injection, one ampoule of Sodium bicarbonate Injection and one ampoule of Sodium Chloride Injection are packed in PVC blisters sealed, thermo-formated trays having high rigidity and sufficient impact strength to provide break resistance packaging. The tray along with Instructions for reconstitution and administration of Artesunate Injection should be packed in a box for easy handling, transport and distribution. It shall be fabricated from Millboard/ grey board/ cardboard with a minimum of bursting strength of 300gsm.

Labelling for secondary packaging:	The label on secondary pack shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time. The Primary, Secondary and Tertiary packaging label of Inj. Artesunate kit shall indicate **"NVBDCP, Dte.GHS SUPPLY-NOT FOR SALE"**.
Packing for Shipper Package:	The secondary packages of Artesunate Injection + Sodium Bicarbonate Injection + Sodium Chloride Injection and that of Syringes + needles shall be packed in weather resistant triple walled insulated corrugated 5-ply cartons, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade material. Burst factor of individual ply should be not less than 22. GSM of the shipper should be not less than 13 Kg/cm^2. Overall dimensions of the carton should be such that the product does not get damaged during transportation and storage.
Shelf Life of Artesunate Injection Kit:	Minimum 24 months, at least $5/6^{th}$ of the shelf life must remain at the time of shipment. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package. The expiry date of the Artesunate Injection Kit shall be the same as that of Artesunate Injection being the constituent of product with the shortest shelf life.
Numbering of shipper packaging:	All boxes should be numbered consecutively. Shipping documents should be included in the box labeled number 1 (consignee wise).
Qualification of the Manufacturer:	The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to GMP standards. In case of medical devices the manufacturing facility must conform to the standards given in ISO 13485 and Schedule M-III of Drugs & Cosmetic Act.
Recalls	If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.
Model Inserts:	A common insert containing information of all products included in Inj. Artesunate Kit with regards to use, adverse drug reactions and precautions (to be observed while taking the drug) should be a part of each secondary pack.

Technical Specifications approved as on 03 October 2022

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