

Canada bans three Indian API manufacturers

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Singapore: Health Canada, national health agency, has banned the import of health products from three different companies in India including Apotex Pharmachem India Private Limited (APIPL), Apotex Research Private Limited (ARPL) and IPCA Laboratories after USFDA spotted data integrity issues at their sites.

Health Canada has raised its concern on the manner in which data are collected and reported, raising serious doubts about the quality and safety of finished products and APIs produced at these sites. The agency has not recalled any of the products but has stopped imports as a temporary precautionary measure until it is satisfied of the processes followed at these sites.

According to Health Canada, the action would apply to finished products from Apotex and active pharmaceutical ingredients (APIs) and products made with APIs from APIPL and IPCA.

Health Canada has clarified that certain medically necessary products may be excluded from the action on the condition that they are tested by an independent third party before being released for use or sale.