PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Elemental Impurities Risk Assessment for Purified water

Material Name (with type of Grade for Excipient): Purified Water

DMF/CEP number (if applicable): --

Source/Type of Excipient: Natural

Elemental Impurity Information:

Regarding the ICH Q3D Class 1 and Class 2A metals, a limited number of batches (three consecutive day samples from outlet of purified water generation system) have been tested to establish typical level of these metals. These samples were collect from the outlet of purified water generation system. The results are in the table below in the standardized format established by the ICH.

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Specific-ation limits (ppm)	ICH limit (ppm) for Oral dosage form	Analytical Method Used (and Limit of Detection/Limit of quantification if Available) (e.g. ICP)	Is Pharmacopoeial method used (eg. USP/ Ph.Eur)	Comments regarding source of information (i.e. if intentionally added Catalyst or reagent, /Raw material/starting material/from manufacturing equipment, container closure systems; frequency of testing, process understanding, etc.)
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	Below detection limit	0.0020	0.5	IS:3025(P-65)2014	--	Based on the three consecutive days production sample analysis
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	Below detection limit	0.0020	0.5	IS:3025(P-65)2014	--	Based on the three consecutive days production sample analysis
Arsenic	As	1	Yes ☐	No ☒	Unknown ☐	Below detection limit	0.0020	1.5	IS:3025(P-65)2014	--	Based on the three consecutive days production sample analysis
Mercury	Hg	1	Yes ☐	No ☒	Unknown ☐	Below detection limit	0.0020	3	IS:3025(P-65)2014	--	Based on the three consecutive days production sample analysis
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	Below detection limit	0.0020	5	IS:3025(P-65)2014	--	Based on the three consecutive days production sample analysis
Vanadium	V	2A	Yes	No	Unknown	Below	0.0020	10	IS:3025(P-	--	Based on the three consecutive days production sample analysis

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			☐	☒	☐	detection limit			65)2014		
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	Below detection limit	0.0020	20	IS:3025(P-65)2014	--	Based on the three consecutive days production sample analysis

Conclusion- From the above results it can be concluded that the all the elemental impurities obtained in the purified water are far below the control Threshold. Hence; no additional control is required. Furthermore, it can be concluded that the purified water complies the requirements of ICH Q3D.